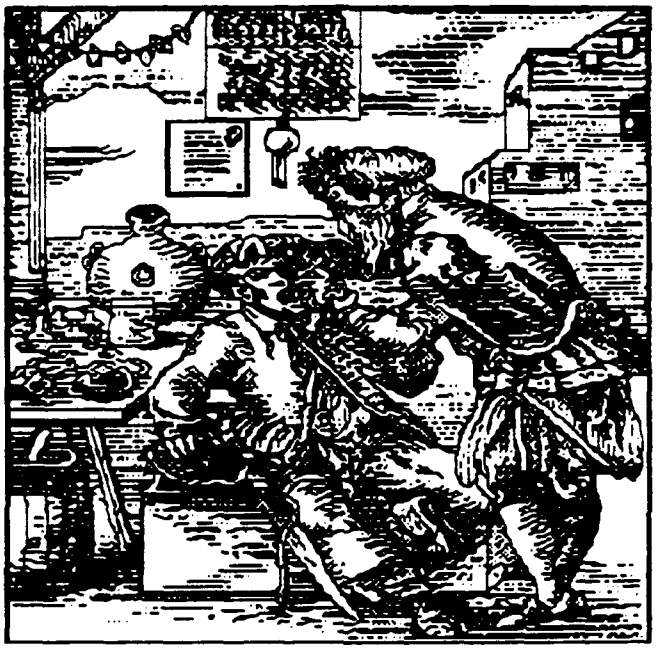
CLINICAL INVESTIGATION PROGRAM REPORT



DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER

FT GORDON, GA 30905

FY 90

CLINICAL INVESTIGATION

PROGRAM REPORT

1 October 1990

CONTROL SYMBOL: RCS MED-300 (R1)

Department of Clinical Investigation
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905-5650

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FOREWORD

The cover of our annual report this year depicts a medieval practitioner operating i he oral cavity of a patient. By his dress one would expect that he is a bar r-surgeon who includes dentistry among his surgical skills. One such fifteenth century surgeon, Pietro d'Argelata, was a student of Guy de Chauliac and was skilled in dentistry in addition to wound management, stone removal, hernia repairs, and assorted other procedures. At the height of the Renaissance, the papal surgeon to Julius II, di Vigo, wrote a sixteenth century treatise, Practica in Chirurgia, in which he includes a section on dentistry. It incorporates assorted applications for toothache such as alcohol, oil of vitriol, and belladonna alkaloids. He recommends the boring, filing and scraping of carious teeth and the subsequent filling by gold leaf.

One of the oldest extant dental treatises dates to the 23rd century BC and is on a Sumerian cuneiform tablet. It prescribes henbane seeds in a gum mastic for toothache in a carious tooth. Mandrake, poppy, and cannabis were popular recommendations for relief also. The curious idea of a relationship between worms and caries dates to this period and surfaces in Hindu, Egyptian, Chinese, Roman, and Mayan writings. The ancient Hindus also had potions to abolish pain and induce sleep in treating dental conditions. They recommended brushing of teeth and the removal of bad teeth. The ancient Chinese suggested mouthwashes, including urine, for dental hygiene. Not surprisingly they used acupuncture for analgesia of toothache. The Egyptians of the 25th century BC must have known of dental prostheses since one has been dated to that era. The early Etruscans were especially skilled in bridgework with remarkable specimens still preserved in museums.

Despite the availability of these ancient treatments, no further progress seems to have occurred until the general advance in surgery in the eighteenth century. Dr. John Hunter, a Scottish surgeon, published his Natural History of the Human Teeth in 1771. This first scientific study classified teeth as to molars, incisors, cuspids, and bicuspids. It discussed malocclusion and appliances for its correction. It also recommended the complete removal of pulp prior to the filling of teeth. Dr. Hunter's subsequent works dealt with unrelated topics of venereal disease, inflammation, physiology, and gunshot wounds. Slightly earlier in the 18th century, Pierre Fauchard and Philipp Pfaff had written treatises on dental subjects. These three are the founders of modern dentistry although they were considered simply surgeons of the day.

Not until the 19th century did dentistry generally begin to emerge from a trade status practiced by barbers and others and emerge as a profession. Although some surgeons practiced dentistry, the bulk of the craft was performed by less skilled practitioners. Sir John Tomes in England secured that change in founding the Odontological Society (1856),the Dental Hospital (1858), and the Dental Act (1878) which made the education and registration of dentists compulsory. However, the 19th century saw the greatest advances in dentistry occurring in America. The hand mallet, vulcanite artificial dentures, the rubber dam, bridge work, amalgam use, porcelain inlays, orthodontic devices, scraping of teeth for periodontal disease, and others were all of American origin.

In the 19th century, one of dentistry's greatest contributions served as a repayment of sorts for earlier advances of the general surgeons to dentistry. Dr. William T.G. Morton made a historic contribution to surgery by providing ether anesthesia to a surgical patient of Dr. Warren's at the Massachusetts General Hospital on October 16, 1846. Six years earlier, in 1840, William Morton had enrolled in the first class of the first college of dentistry in the United States, the Baltimore College of Dental Surgery. Upon graduation he went into partnership with Dr. Horace Wells in Boston. Dr. Wells had experimented with nitrous oxide for dental anesthesia in 1844. A fatal case some years later caused him to withdraw from practice and eventually end his life. Dr. Morton, meanwhile, had decided to go to medical school at Harvard while still supporting himself as a dentist. There he continued his interest in anesthesia, eventually learning that ether had desirable properties lacking in nitrous oxide. His dental research on new ways to fasten artificial teeth upon a gold plate in the mouth required the use of anesthesia. He experimented with opiates but had been stymied by excessive vomiting. Dr. Morton's desire for a patent on the process caused him to be quite secretive about the whole procedure and eventually led to some bitter feuds with Dr. Wells and his chemist-mentor at Harvard, Dr. Jackson. The demonstration was a success in spite of Dr. Morton's late arrival on the crucial day owing to some problems with the apparatus for the ether's preparation. Word of the success spread quickly and ether use was soon widely adopted in leading academic institutes. An earlier use of ether in surgery by Dr. Crawford W. Long in 1842 was equally successful, but its occurrence in rural Georgia did not stir the popular interest in the same manner as the Harvard example two years later. Nonetheless, Georgia can claim the precedent for ether use just as Virginia does for Thanksgiving Day, but Massachusetts still receives the publicity.

The active presence here at DDEAMC of dental residencies in the specialties of periodontics, endodontics, prosthodontics, and oral surgery has made important contributions to the biomedical research role of this institution. These topics deal with the contemporary problems of pain management and mechanisms, bone metabolism, microbiology, immunologic changes in HIV infections, inflammatory responses, connective tissue attachment, and wound healing. At the tissue and cellular level the interests of dentistry and medicine merge back into a common purpose which is shared by all of the practitioners of the healing arts. This scholarly form of dentistry resists the sometimes tendencies to compartmentalize dentistry into a narrow craft with few or no applications to medicine and surgery. The recent solidification of a Masters of Science in Oral Biology through the Medical College of Georgia School of Dentistry as part of the residency in periodontics and endodontics is a major step in the academic growth of these programs. Clinical Investigation staff members serve as faculty on the thesis committees.

Other areas of progress at DDEAMC include real steps toward a new animal/ laboratory facility for FY 93. In the past this project would slip further away each year. We are now ready for preliminary design considerations. If construction remains on schedule, we may be able to move into a new facility before the old one collapses from the termites. We are proud of the fact that a

paper from here was accepted for presentation at the Army Science Conference in 1990. It was the only one from HSC to be represented. Despite cutbacks, limitations, and problems, we are able to approach this new decade with confidence that we are preparing for solid growth in scientific and academic achievement. We are deeply grateful for the leadership and encouragement provided by our commanding general, Brigadier General James E. Hastings, and by the deputy commanders and department chiefs. The level of cooperation for the common good that exists at Eisenhower is one of the secrets of success by encouraging the best from each contributor. Each practitioner of the healing arts has a common goal from specialists in the oral cavity to the rectum, from healers of the body to the psyche, from the users of procedures to the users of insight, from clinicians to the investigators. The complexity of this tapestry of interdependence is held together by enlightened leadership's concern for the warp of excellence and the woof of mutual respect.

KENT M. PLOWMAN
COL, MC
Chief, Department of Clinical Investigation

UNIT SUMMARY - FISCAL YEAR 1990

A. Objective.

The Department of Clinical Investigation is responsible to the Deputy Commander for Clinical Services for providing the facilities and atmosphere of inquiry necessary to support and stimulate both basic and clinical medical investigation within DDEAMC.

B. Technical Approach.

All research, investigational, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-38, AR 40-7, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with these applicable regulations.

C. Staffing.

Name	Rank	MOS	Title
Plowman, Kent M.	COL	61F00	Chief
Morse, Brent C.§	CPT	64F00	Veterinarian
Hofmann, John R.*	MAJ	64F00	Veterinarian
Sutherland, Donald E.	MAJ	68C00	Biochemist
Turgeon, David K.	MAJ	68A9B	Immunologist/Microbiologist
Nead, Charles L.	SSG	92B30	NCOIC, Med Lab NCO
Decker, Rodney**	SSG	92B30	Med Lab Sp
Morris, Kathy	SGT	92B20	Med Lab Sp
Rodriguez-Morales, Janet	SGT	92B20R	Med Lab Sp
Nelson, Manuela***	SGT	91T20	Senior Veterinary Sp
Ellis, Saundra	SPC	91T10	Veterinary Sp
Marchand, Rita	SPC	91T10	Veterinary Sp
Horner, Jack A.	GM13	01301	Asst C, S. Res Histologist
McPherson, James C. III, PhD	GS12	01320	Biochemist
Runner, Royce R.	GS11	00644	Medical Technologist
Martinez, Rosina	GS7	00303	Protocol Coordinator
Searles, Rosa	GS6	00404	Biological Lab Technician
Dalton, Beatrice	GS4	00312	Clerk-Steno
Arensman, John B.	GS12	00701	Veterinarian (WAE)
Hinton, Alma	GS7	00404	Biological Lab Technician (Detail to Pathology)
Zadinsky, James	GS7	01531	Stat Asst (Temporary)
Challenger, Patricia	GS11	00644	Study Coordinator (5-yr term Dermatology Svc, NIH Grant)
Chuang, Augustine H.	GS9	00644	Medical Technologist (3-yr USA MRDC Contract)

Officer: 4 authorized; 5 required; 4 assigned
Civilian: 7 authorized; 13 required; 7 assigned
Enlisted: 5 authorized; 9 required; 5 assigned

*Retired Nov 89; **ETS Apr 90; ***Transferred May 90; §Assigned Sep 90

D. Funding.

Type	Fiscal Year 89	Fiscal Year 90
Civilian personnel to include benefits	216,387.00	227,469.00
Consumable supplies	67,860.00	85,428.00
Civilian contracts to include consultants	4,857.00	4,233.00
TDY*	17,073.00	14,962.00
Publications	4,087.00	2,095.00
CEEP	4,953.00	49,021.00
MEDCASE	145,920.00	101,980.00
Military	506,405.00	526,740.00
Total	967,542.00	1,011,928.00

*Includes Clinical Investigation personnel plus other paper presentations from Dwight David Eisenhower Army Medical Center staff and residents.

Grant Funding:

NCI - "Use of Isotretinoin in Prevention of Basal Cell Carcinoma."
FY 90: $58,804.00

MRDC - "The Capsule of S. aureus: Bone Tropisim, Adherence and Host Immunity (Rat Model)."
FY 90: $62,658.00

MRDC - "Non-ionic Surfactants in the Treatment of Third Degree Burns in Rats."
FY 90: $45,376.00

Jackson Foundation - "Evaluation of Nitroglycerin Therapy in Patients with Asymptomatic Coronary Artery Disease and Silent Ischemia."
FY 90: $20,000

E. Progress.

Protocol Disposition FY 90

	Completed	Terminated	Ongoing to FY 91
FY 78	-	-	2
FY 83	-	-	3
FY 84	1	-	2
FY 85	-	1	1
FY 86	-	-	1
FY 87	2	1	4
FY 88	1	2	8
FY 89	16	7	18
FY 90	4	4	31
	24	15	70

Number of resident and fellowship programs: 15
Number of residents and fellows with approved protocols: 44
Number of approved protocols held by this group: 40

Other training programs that use Clinical Investigation: Transitional Internship, Anesthesiology Course, Graduate Students.
Number of approved protocols held by this group: 3

Number of hospital staff members with approved protocols: 49
Number of approved protocols by this group: 81

Drug evaluation/comparison studies: 13
Treatment evaluation/comparison studies: 52

RESEARCH AWARDS

Recipient of

The Eighth Annual DDEAMC Resident Reseach Award
was

Captain Louis K. Duchin, MC, Psychiatry Resident
for his paper

"Cognitive Impairment in HIV-Seropositive Soldiers: Relation to Mood and Immunosuppression"

The paper based on Protocol #87-10 was presented at the Armed Forces Psychiatry Course, Menninger Conference, received outstanding paper by a resident award, Topeka, KS, April 1990; and at APA, New York, NY, May 1990 as an invited paper.

Recipient of

The Fourth Annual Dental Activity Resident Research Award
was

Major Rodger A. Lawton, DC, Periodontal Resident
for his paper

"The Relationship Between the Frankfort-Mandibular Plane Angle and Lateral Disclusion Patterns," based on Protocol #89-34.

INSTITUTIONAL REVIEW COMMITTEE

Clinical Investigation and Human Use Members

Chief, Department of Clinical Investigation, Chairman
Chief, Department of Medicine
Chief, Department of Surgery
Chief, Pharmacy Service
Research Director, Dental Activity
Chief, Department of Ministry & Pastoral Care
Chief, Nursing Education & Staff Development
Signal Center Representative, Ft Gordon, Georgia
Chief, Department of Pathology
Research Director, Department of Family Practice
Research Director, Department of Psychiatry & Neurology
Medical Center Judge Advocate
Chief, Nuclear Medicine Service
Chief, Medical Records Administration Section

Animal Use Members

Chief, Department of Clinical Investigation, Chairman
Chief, Department of Medicine
Chief, Department of Surgery
Veterinarian, Department of Clinical Investigation
Signal Center Representative, Ft Gordon, Georgia

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DENTAL ACTIVITY

* * * * *

Code:

O - Ongoing
C - Completed
W - Withdrawn
T - Terminated

P - Published
PR - Presented

PUBLICATIONS FY 90

DEPARTMENT OF CLINICAL INVESTIGATION

Runner RR, Nead CL, Paustian PW Jr, McPherson JC III, McPherson JC Jr: P_{50} Improvement in normal rats following treatment with Pluronic F-108. (Abstract) Amer Chem Soc, SE Region 1989; 41:158. (C)

McPherson JC Jr, Paustian PW, Jr, Runner RR, McPherson JC III: Pluronic F-127 alters skin temperature in burned area of rats as measured by thermography. (Abstract) Amer Chem Soc, SE Region 1989; 41:159. (C)

McPherson JC III, Paustian PW Jr, Nead CL, McPherson JC Jr: Temporary improvement of P_{50} values following administration of a short acting surfactant in burned animals. (Abstract) Amer Chem Soc, SE Region 1989; 41:159. (C)

Nead CL, McPherson JC III, Runner RR, Paustian PW Jr, McPherson JC Jr: Enhanced P_{50} values by Pluronic F-88. (Abstract) Amer Chem Soc, SE Region 1989; 41:159. (C)

Kaup MR, McPherson JC Jr, McPherson JC III, Runner RR: The in vitro evaluation of burn protectivbe agents on oxyhemoglobin dissociation. (Abstract) Proc Ann Mtg SE Sec Soc Exp Biol Med 1989; 14:11. (C)

McCausland KE, McPherson JC Jr, Runner RR, McPherson JC III: Pluronic polyols alter red blood cell deformability in rats receiving third degree burns. (Abstract) Proc Ann Mtg SE Sec Soc Exp Biol Med 1989; 14:11. (C)

Garrett T, McPherson JC III, Runner R, McPherson JC Jr: Protective effect of albumin and pluronic F-68 on red blood cell "wash hemolysis." (Abstract) Proc Ann Mtg SE Sec Soc Exp Biol Med 1989; 14:11. (C)

McPherson JC Jr, Nead CL, Runner RR, McPherson JC III: P_{50} of whole blood treated in vitro and in vivo with poloxamer 338, a non-ionic surfactant. (Abstract) Proc Ann Mtg SE Sec Soc Exp Biol Med 1989; 14:15. (C)

McPherson JC Jr, Runner RR, McPherson JC III: Red blood cell deformability following a trioctanoin meal. (Abstract) GA & SC Nutr Council Abstr Sec 1990; 5. (C)

Nguyen P, McPherson JC Jr, Runner RR, McPherson JC III: Comparison of olive oil and menhaden oil on red blood cell deformability during alimentary lipemia. (Abstract) GA & SC Nutr Council Abstr Sec 1990; 5. (C)

Doetsch GS, Johnston KW, Hannan CJ Jr: Physiological changes in the somatosensory forepaw cerebral cortex of adult raccoons following lesions of a single cortical digit representation. Exp Neurology. (In Press) (C)

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Buxton TB, Rissing JP, Horner JA, Plowman KM, Scott D., Sprinkle JJ, Best GK: Binding of a Staphylococcus aureus bone pathogen to type I collagen. Microbial Pathogenesis 1990; 8:441-448. (C)

McPherson JC III, Guy SC, O'Neal R, McQuade MJ, Van Dyke TE, McPherson JC Jr: in vitro attachment of human fibroblasts to endosseous implant materials. (Abstract) FASEB J 1990; 4:A1082. (C)

Alleyn CD, O'Neal R, Strong SL, Scheidt MJ, Van Dyke TE, McPherson JC III: in vitro human gingival fibroblast attachment to chlorhexidine treated tooth root surfaces. (Abstract) FASEB J 1990; 4:A1082. (C)

McPherson JC Jr, Paustian PW, Plowman KM, Runner RR, McPherson JC III: Delayed early wound contracture (enhanced wound healing) in burned rats treated with Pluronic F-127. (Abstract) FASEB J 1990; 4:A740. (C)

Plowman KM, McPherson JC III, Runner RR, Paustian PW, McPherson JC Jr: Altered red blood cell deformability in burned rats given multiple doses of Pluronic F-127. (Abstract) FASEB J 1990; 4:A819. (C)

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Paustian PW, McPherson JC III, Runner RR, Plowman RM, Haase RR, McPherson JC Jr: Intravenous pluronic F-127 reduces inflammatory reaction and enhances burn wound healing in rats. (Abstract) Ann Emerg Med 1990; 19:456. (C)

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Sutherland DE, Robinson MD: Urine caffeine levels in patients on a buspirone-assisted smoking cessation program. (Abstract.) Clin Chem 1990; 6:1168.

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Luccy CT, Weller RN, Kulild JC: An evaluation of the apical seal produced by lateral and warm lateral condensation techniques. J Endodon 1990; 16(4):170-172.

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DEPARTMENT OF PATHOLOGY

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Hamilton JN, Thompson SH, Scheidt MJ, McQuade MJ, Van Dyke T, Plowman K: Correlation of dorsum tongue subclinical candidal colonization with the Walter Reed Staging Scheme for HIV-1 patients. Oral Surg, Oral Med, Oral Pathol. (In Press)

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Francis GL, Hoffman WH, Gala RR, McPherson JC III, Zadinsky J: A relationship between neonatal breast size and cord blood testosterone level. Ann Clin Lab Sci 1990; 20(4):239-244.

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DEPARTMENT OF PSYCHIATRY & NEUROLOGY

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DEPARTMENT OF SURGERY

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Martindale RG: Nutritional support of the neurotrauma patient. Medical College of Georgia, Augusta, GA, 13 Sep 1990.

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Orthopedic Service

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Barja RH: Combined Peruvian - USA fracture trauma course. Lima, Peru, 26-30 Jun 1990.

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DETAIL SUMMARY SHEETS

Detail Summary Sheet

Date: 11 Oct 90 Prot No.: 84-50		Status: Ongoing
Title: A Scanning and Transmission Electron Microscopic Study of the Effects of Cadmium on the Early Developmental Components of the Craniofacial Region of the Hamster Embryo		
Start Date: Jul 84		Est Comp Date:
Principal Investigator(s) Jack A. Horner, BS Thomas F. Gale, PhD		Facility: Eisenhower Army Medical Center Medical College of Georgia
Dept/Svc: Clinical Investigation Anatomy Dept, MCG		Associate Investigators:
Key Words: Electron microscopy, Cadmium, Teratology		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results Sep 90 Continue

Study Objective: To utilize electron microscopy to compare the fine structural features of the component tissues of 13 different regions of the face at selected timed-intervals during the early development of the craniofacial region in cadmium-exposed vs control hamster embryos.

Technial Approach: Cadmium sulfate solution is injected (IV) into timed pregnant golden hamsters on the eighth gestation day (8 AM) and embryos are collected at selected times during the period of early facial development, i.e., day 8 at 6PM; day 9 at 8AM; day 10 at 8 AM; day 10 at 6PM; day 11 at 8 AM. The embryos are fixed, dehydrated by critical point drying, coated with gold, and examined and photographed in the scanning electron microscope. Comparisons between embryos from the control (sham-injected) and experimental (cadmium-injected) pregnant hamsters will reveal the teratogenic effects of cadmium on the developing embryonic face. The comparisons will be both qualitative and quantitative. Collection of the quantitative data on surface area measurements will be accomplished by utilization of a computer interfaced morphometric digitometer system.

Progress: Work on this project has resumed with a re-examination of the earlier samples. These samples have been reprocessed to permit morphometric studies of the lateral view to determine the third dimensional extent of the teratologic changes. The present and future data will be subjected to a more rigorous treatment by the application of new computer software to determine the volume of discrete facial prominences.

Detail Summary Sheet

Date: 10 Oct 90 Prot No.: 87-16		Status: Ongoing
Title: The Utility of the 60-Kilodalton Oncofetal Tumor Marker in the Monitoring of Treatment of Cancer Patients.		
Start Date:		Est Comp Date:
Principal Investigator(s) Donald E. Sutherland, MAJ, MS		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation, Surgery		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Jan 90 Review Results Continue

Study Objective: To determine if the 60-kilodalton tumor marker is effective in monitoring the tumor status of patients with various types of cancer by determination of its activity post-surgery.

Technical Approach: Patients undergoing surgery for colon, breast, and lung cancer, and melanoma will have plasma drawn prior to surgery and 48 and 72 hours after surgery. The 60-kilodalton oncofetal tumor marker will be determined in all specimens and compared with results obtained in healthy volunteers. If possible, cancer patients will have plasma drawn and assays run on followup examinations, three to six months after surgery.

Total number of subjects enrolled to date: 47
Total number of subjects enrolled for reporting period: 35

Progress: Due to the rotation of the surgical resident and the problems associated with obtaining specimens from the Department of Surgery, no new surgical specimens were received during this reporting period. With the addition of a new oncologist to the staff who has taken an interest in this protocol, 33 patients with hematological cancers have been added. Since the treatment periods for these patients normally last upwards of six months, we are just now completing the post-treatment series for a few of these patients. Assays will be performed on the whole series as they are completed. We have also expanded the protocol to include AIDS patients with Kaposi's sarcoma. Two of these patients have been added to the protocol. Analysis of their plasma specimens indicated quantities of the 60-kilodalton tumor marker 9SW60). These results may be expanded into a separate protocol designed to look for SW60 in the plasma of AIDS patients.

Detail Summary Sheet

Date: 21 Sep 90 Prot No.: 87-17 Status: Completed
Title: Red Cell Protection in Major Third Degree Burns in Rats.

Start Date: Feb 88		Est Comp Date: Sep 90
Principal Investigator(s) Paul W. Paustian, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation		Associate Investigators: James C. McPherson III, PhD Randall R. Haase, MD, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To analyze in an animal model the protective effect of surfactants in preventing hemolysis and erythrocyte cell membrane damage following exposure of the subject to a 50-80% burn surface area. To correlate any beneficial effect with an optimum plasma concentration of the surfactant.

Technical Approach: The established method of Adams et al (Circ Shock 1981; 8:613) will be used. Serial blood samples will be drawn 1 hour post burn and at six hour intervals through 36 hours and analyzed for hematocrit, hemolysis, red blood cell fragility and elasticity. Six groups of animals will represent: 1) control - sham, 2) control - without blood drawn, 3) surfactant IV, 30 min post burn, 4) surfactant IV, 60 min post burn, 5) surfactant IV 90 min post burn, and 6) surfactant IV immediately prior to burn.

Progress: This protocol has made a significant contribution resulting in eleven abstracts being published and eleven presentations at scientific meetings. It has been the basis for the approval of four additional protocols, two by residents. A third degree burn model has now been well established and is being utilized to study the effects of various drugs and drug treatments on burn wound healing and acute interventions. Protective effects on RBCs of several pluronic polyols have been observed in vivo with several pluronic polyols.

Detail Summary Sheet

Date: 11 Oct 90	Prot No.: 87-40	Status: Ongoing
Title: Pathology Applications of X-ray Spectrometric Microanalysis.		
Start Date:		Est Comp Date:
Principal Investigator(s) Jack A. Horner, BS		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation/Pathology		Associate Investigators: Phyllis Brewer
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To utilize specimens obtained during routine surgical and autopsy pathology examinations to gain expertise in applications of x-ray spectrometric microanalysis.

Technical Approach: Tissue specimens without known abnormalities of elemental composition are selected from the daily laboratory workload. These are examined for establishment of baseline spectrometric spectra following the use of various fixatives. These spectra can then be compared against specimens with known or suspected elemental abnormalities.

Manpower demands have been met by the principal and associate investigators alone.

Funding has not required the allocation of any additional funds.

Progress: Additional samples were analyzed and cataloged into the data base as they became available. Preluminary findings have indicated that buffer and fixative components are so abundant that they mask the trace contents of the tissue. The state of the art solution to this problem is the use of cryofixation and frozen sections to totally avoid fixatives and buffers. These techniques will be employed as equipment becomes available.

Detail Summary Sheet

Date: 21 Sep 90 Prot No.: 89-4		Status: Completed
Title: The Protective Effect of Surfactants in Microvascular Burn Injury to Rats.		
Start Date: Dec 88		Est Comp Date: Aug 90
Principal Investigator(s) Paul W. Paustian, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation, Pathology		Associate Investigators: James C. McPherson, III, PhD Kent M. Plowman, MD, LTC, MC Tu H. Nguyen, MD, LTC, MC Randall R. Haase, MD, CPT, MC James C. McPherson Jr., MD Royce R. Runner, MT
Key Words: Surfactants Microvasculature Burn treatment		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $1500	Periodic Sep 89 Review Results Continue

Study Objective: To study potential protective effects of several surfactants on the microvascular bed in skin burns.

Technical Approach: Rats receiving an 8% body surface area third degree burn receive IV non-ionic surfactants 30 min post burn. Evaluations of drug effectiveness in enhancing are made by measuring mechanical and osmotic fragility of RBC's, RBC deformability, wound size, and temperature and histology.

Progress: This protocol has already resulted in the presentation of five papers at national meetings, one major paper submission to a national journal, eight abstracts accepted for presentation at regional meetings. In addition, two major publications are in preparation from this protocol. Major advances in major third degree burn wound care have been indicated fromt he information gained by these expe iments. Specifically, Pluronic F-127 has been shown to be extremely beneficial in preventing wound contraction, edema, vascular necrosis, fibrin deposition, perivascular fibrosis, red cell extravasation in the dermis, submucosa and beneficial wound temperature changes. These findings are consistent and imply that F-127 may play a role in the preservation of the integrity of the microvascular bed and a diminuation of the inflammatory response. To date, the experiments outlined in Group 1, single dose, 48 hour experimental period have been completed.

Detail Summary Sheet

Date: 16 Oct 90 Prot No.: 89-14		Status: Ongoing
Title: The Capsule of S. aureus: Bone Tropism, Adherence and Host Immunity (Rat Model)		
Start Date: Jul 89		Est Comp Date: Sep 92
Principal Investigator(s) Kent M. Plowman, MD, PhD, LTC, MC		Facility: Eisenhower Army Medical Center & VAMC, Augusta
Dept/Svc: Infectious Disease, MCG; Clinical Investigation: Research Dept, VA		Associate Investigators: J.P. Rissing, MD, VAMC Gary K. Best, PhD, MCG Jack A. Horner, BS Thomas Buxton, MS, MBA
Key Words: Osteomyelitis, S. aureus, Bacterial capsule		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 89 Review Results Continue

Study Objective: Contrast laboratory strains of S. aureus for adherence to type 1 collagen in vitro and in vivo.

Technical Approach: Otherwise isogenic S. aureus strain SA-1 capsular variants will be compared for collagen adherence using the ^{125}I-collagen adherence assay. A second assay measures S. aureus adherence to demineralized bone. We will examine capsular variants for colonization of traumatized rat tibiae using our experimental model.

Progress: S. aureus surface protein adhesin, not capsule, was deemed responsible for collagen binding using the ^{125}I-collagen adherence assay. These results were published recently in Microbial Pathogenesis (8:441, 1990). Therefore, otherwise isogenic S. aureus strain variants for surface collagen-binding protein were sought after. We used transposon mutagenesis of a phage and antibiotic susceptible clinical collagen-binding osteomyelitic isolate; strain 16. Twenty six hundred ery^r subclones (attesting to Tn551 insertion) were screened for defective type I collagen binding. A mutant named NB1^{Cn-ncg}, was identified and compared to parent for phenotypic enzymatic, biochemical, antibiotic susceptibility and binding studies. Results from this work suggest we have successfully isolated an isogen mutagenicized for collagen binding. We are currently contrasting the two for binding kinetics to collagen and adherence to bone chips in vitro. We are also using an in vivo rat tibial colonization model of acute hematogenous osteomyelitis.

Detail Summary Sheet

Date: 10 Oct 90 Prot No.: 89-17		Status: Ongoing
Title: Pilot Study: Determination of the Potential of Carcinoma Cells Grown in Culture as a Source of the 60-Kilodalton Oncofetal Tumor Marker		
Start Date: Apr 89		Est Comp Date:
Principal Investigator(s) Donald E. Sutherland, PhD, MAJ, MS		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Attempt to identify carcinoma cells grown in suspension culture as a good source of SW60.

Technical Approach: Various subcultures of carcinoma cells obtained from the American Type Culture Collection will be grown in culture and the spent medium tested for SW60 by traditional methods. Cells which demonstrate secretion of SW60 will be held for future scale-up procedures to "manufacture" SW60.

Progress: Traces of the 60-Kilodalton tumor marker (SW60) have been found in all of the cell types cultured, which include leukemias, lymphomas, and colon carcinomas. Although colon carcinoma produces the highest titers of SW60 in vivo, as yet none of the cells cultured have hbeen a major producer of SW60. Further cell lines will be tested.

Detail Summary Sheet

Date: 10 Oct 90	Prot No.: 89-38	Status: Ongoing

Non-Ionic Surfactants in the Treatment of Third Degree Burns in Rats.

Start Date:		Est Comp Date:
Principal Investigator(s) James C. McPherson III, PhD		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation		Associate Investigators: James C. McPherson, Jr, MD Kent M. Plowman, MD, LTC, MC Paul W. Paustian, MD Randall A. Haase, DO, MAJ, MC Royce R. Runner, MT (ASCP)
Key Words: Surfactant Burn treatment		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 90 Review Results Continue

Study Objective: To study potential protective effects of non-ionic surfactants in the treatment of third degree burns.

Technical Approach: Effect of single and multiple doses of non-ionic surfactants give IV thirty minutes following a third degree burn will be studied to evaluate burn wound healing.

Progress: A class of non-ionic surfactants, the Pluronic polyols, have membrane sensitive effects and low toxicity in mammals. An isotonic solution of Pluronic F-127 (12mM at 8 ml/kg bd wt), administered IV, was compared with normal saline controls in a standard full thickness scald burn of 8-10% body surface area in outbred male rats. Injections were at 30 min post burn to simulate emergency response times. Responses were followed by infrared thermography, photography, wound area, histology, and blood rheology. Thermography detected a clearly cooler (1°C) wound area in treated animals at 90 min post burn, suggesting a lessened acute inflammatory response. By 48 hrs post burn, the treated rats had significantly less wound contraction, less edema, improved P_{50} and improved microvascular blood flow as detected by thermography of the wound (1°C warmer) area. Histologically, improved tissue viability showed reduced vascular necrosis, fibrin deposition, perivascular fibrosis, edema and erythrocyte extravasation in the dermis and cutis in the F-127 treated animals relative to saline treated controls. Positive rheological benefits were also detected. A small, but significant positive shift in the P_{50} enhanced oxygen delivery. Erythrocytes were protected against mechanical fragility and had decreased deformability. Early F-127 appears to preserve the viability of the tissue immediately adjacent to and extending into the burn area by reducing inflammatory damage and promoting recovery of underlying tissue. No apparent gross toxicity on autopsy has been noted. Membrane stabilization of vascular endothelium or of a key inflammation cell are possibilities. The striking effect on reduction of edema in the burn wound and adjacent tissues could be critical for microvascular salvage and may extend protection to other damaged tissues.

Detail Summary Sheet

Date: 10 Oct 90 Prot No.: 89-46		Status: Ongoing
Title: Effects of Non-ionic Surfactants in Sunburns Using a Rat Model.		
Start Date:		Est Comp Date:
Principal Investigator(s) Kent M. Plowman, MD, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation/Pathology		Associate Investigators: James C. McPherson, III, PhD James C. McPherson, Jr., MD Paul W. Paustian, MD Randall R. Hasse, MD, CPT, MC Royce R. Runner, ASCP
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate possible protective effects of non-ionic surfactants in ultraviolet induced first degree skin burns using an albino rat model.

Technical Approach: Male, Sprague-Dawley rats weighing greater than 320 gm will be used. A 3 x 6 cm area will be exposed to UV light at 3x the minimal erythemal dose. This study is based on earlier work which showed that the non-ionic surfactant F-127 injected shortly after a full thickness burn of the skin could reduce the amount of damage tot he underlying tissue and speed healing. The mechanism of this protective effect is not yet known. This study is an attempt to isolate the steps in the process by examining first degree burns to see if these same protective effects would also work with skin which is merely injured.

One of the key early steps in wound response is edema formation. This swelling of the injured tissues seems to be a step that is reduced by the F-127. Since this occurs in the first degree burns as well, we are looking to find out if it will prevent this edema here.

The study is designed to minimize the number of rats required. The first phase will examine the response using the intravenous form of the drug as in the other studies in which it is known to work. If it does not have an effect here, the study will be terminated. If it is successful, we will continue with methods to apply the drug topically and have it absorbed either across the burned membrane directly or with another drug, dimethyl sulfoxide, to help with penetration.

The rats to be used are animals which were not used in a larger study because they had outgrown the weight restrictions of that study. These animals would have been euthanized otherwise and not have contributed to scientific value. The rats will be under anesthesia while they are under the ultraviolet lamp

and for treatment. If they show evidence of pain, they will be given the narcotic stadol for pain throughout the remaining 48 hours of the observation phase of the study. They will be euthanized at the end of 48 hours by standard anesthesia overdose. Autopsies will be done. This study will provide valuable information to supplement the larger third degree burn project. Most real burns involve areas of first degree as well. Besides new insight into the way that burn healing can be influenced, we will learn whether this drug will affect the less serious burns through faster healing by reducing the amount of marginal tissue destruction.

Progress: Sunburn, as known in man and non-rodents, may have either a progression of events which results in the sunburn which are different than those which occur in man or the manifestations by which sunburns are rated in man are different in rodents. While successful sunburns have been produced in rodents, we have been unable to quantify these by the same criteria used for man. These reproducible sunburns are being further investigated in order to establish and define the rodent model.

Detail Summary Sheet

Date: 20 Sep 90	Prot No.: 89-47	Status: Completed
Title: Effect of Sex Hormones on Red Blood Cells in the Rat.		

Start Date: Oct 89		Est Comp Date: Jul 90
Principal Investigator(s) James C. McPherson, III, PhD		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation		Associate Investigators: Kent M. Plowman, MD, COL, MC James C. McPherson, Jr, MD Royce R. Runner, ASCP
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if sex hormones (estradiol and/or progesterone) alter red blood cells in vivo.

Technical Approach: Female rats were castrated at 95 days of age and groups of nine rats were administered 0.1,0.4,1.6 or 6.4 µg/kg/day estradiol or 0.1,1.0 or 8.0 mg/kg/day progesterone dissolved in corn oil. The dosages were divided into two injections daily given s.c., morning and evening, to more closely simulate physiologic conditions. A group of castrated rats receiving corn oil served as controls. At weekly intervals for four weeks, blood was withdrawn via the tail vein and RBC deformability measured using a Technicon Ektacytometer.

Progress: Significant uptake of labeled estrogens and progesterone by human and rat red blood cells (RBC) have been reported. β-Estradiol dipropionate induced changes in the membrane of lipids of erythrocytes in chicks and the uptake of progesterone by rat erythrocytes is 70-85% of the total steroid in contact with the RBC, Progesterone is utilized in the long term storage of RBCs where it protects the RBC membrane. The present study was undertaken to determine if estradiol or progesterone have a physiological or pharmacologic effect on the RBC deformability in castrated rats.

RBC deformability was significantly altered ($p<0.01$) by all doses of estradiol by one week and continued to be significantly altered through four weeks. RBC deformability was not related to the dose of estrogen given. No concentration of progesterone had any effect on RBC deformability through four weeks. Steroids may play an important role in the deformability of RBC which has not been previously recognized. The increased ovarian blood flow observed around the time of ovulation may be due in part to a change in RBC deformability. On the basis of steroid dissociation rates and capillary transit times, RBC associated steroids may be available for uptake by tissues and RBC deformed during transcapillary passage may allow a direct transfer of RBC-associated steroids to the epithelial cell. Exogenous estrogen therapy has proven beneficial in a number of clinical situations. The improvement seen with estrogen therapy may be due in part to the change in RBC deformability as a result of the estrogen therapy. The decreased incidence of cardiac infarcts in premenopausal women and possibly those in estrogen treated post-menopausal women may be due not only to the effect of estrogen on cholesterol metabolism but also due to the change in RBC deformability demonstrated in this study in estrogen treated animals.

Detail Summary Sheet

Date: 18 Oct 90 Prot No.: 89-5		Status: Completed
Title: Evaluation of the Microorganisms Present in Induced Perioimplantitis in the Micro Swine.		
Start Date:		Est Comp Date:
Principal Investigator(s) Judson S. Hickey, MAJ, DC		Facility: Eisenhower Army Medical Center
Dept/Svc: Dental Activity, Clinical Investigation		Associate Investigators: Robert O'Neal, COL, DC Michael J. Scheidt, COL, DC Scott Strong, LTC, DC David K. Turgeon, PhD, CPT, MS
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 89 Review Results Continue

Study Objective: To evaluate the microorganisms present in induced perioimplantitis in the micro swine.

Technical Approach: After an initial period of environmental adjustment of the animals, the jaws and teeth will be radiographed. The mandibular bicuspids will be extracted unilaterally under general anesthesia and the sockets allowed to heal for three months. Then the Branemark implant fixtures will be surgically placed into the edentulous areas of the mandible.

Progress: The inference drawn from the data is that it is possible to create ligature induced peri-implantitis in the micro swine model. This is associated with a distinct microbial shift to a gram negative flora containing pigmenting Bacteroides, and is supported in part, objectively, by steadily increasing mean attachment level and mean probing depth differences between ligatured and non-ligatured implants over the 45-day treatment period studied. and subjectively by the effect that simple cleanings had on the gingival and plaque indices mean differences between ligatured and non-ligatured implants. Although the only statistically significant differences were the probing depth measurements (t x d; $p<.02$), other areas, however, demonstrated significant interactions: i.e. attachment level, gingival and plaque index. It is possible that since the power was very low ($n=2$), only gross differences were detectable during this time frame of treatment. Perhaps, if a longer treatment period was utilized and the variable mean differences continued to steadily increase over time, an alpha value of $p=.05$ would be easily obtainable. On the other hand, possibly an alpha value of $p=.10$ would have been reasonable to assume in this study considering the relatively short treatment time interval combined with the low power of the study.

Detail Summary Sheet

Date: 15 Oct 90 Prot No.: 89-6		Status: Completed
Title: Evaluation of the Sulcular Flora in the Micro Swine in Experimental Periodontitis.		
Start Date: Jun 89		Est Comp Date:
Principal Investigator(s) Jeffrey D. Fowler, MAJ, DC		Facility: Eisenhower Army Medical Center
Dept/Svc: Dental Activity, Clinical Investigation		Associate Investigators: Michael J. Scheidt, COL, DC
Key Words:		Scott L. Strong, LTC, DC David K. Turgeon, PhD, CPT, MS
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 89 Review Results Continue

Study Objective: To collect specimens of subgingival microbiota from the dental sulcus of the adult micro swine in health and in experimental periodontitis and analyze the characteristics of the microbial composition.

Progress: Specimens of oral subgingival microbiota were collected from three Yucatan microswine with advanced, naturally-occurring periodontitis. Heavy deposits of supragingival and subgingival plaque and calculus, 50% or more radiographic alveolar bone loss, gingival inflammation, mobility, gingival recession, and probing depths ranging from 2-8 mm were detected in the seven year old animals. Eight teeth in each animal (two premolars in each of four quadrants) were designated experimental teeth. Prior to the baseline clinical evaluation, subgingival plaque samples were obtained from these teeth and cultured for microbiological identification. Samples were collected with paper points after initial removal of supragingival deposits, dispersed in pre-reduced media, and plated on selective and non-selective media in aerobic, capnophilic and anaerobic atmospheres. Darkfield microscopy was performed to determine relative numbers and proportions of cocci, rods, and spirochetes. All animals were then treated with scaling and root planing. Thirty days after treatment, microbiological samples were obtained and clinical evaluation was performed again. Two animals were then treated with apically-positioned mucoperiosteal flaps, debridement of granulation tissue, and scaling and root planing in two quadrants. microbiological sampling and clinical evaluation were performed 30 days after this treatment. Results revealed that bacteria in clinically healthy sites were primarily facultative nonmotile rods and cocci, including streptococcus intermedius and streptococcus sanguis. Spirochetes were detected in diseased sites, as well as other gram-negative, obligate anaerobes including Bacteroides species such as B. denticola, B. oris, B. bivius, B. oralis, B. uniformis, B. thetaiotaomicron and B. fragilis. There was little change in bacterial populations of diseased sites after scaling and root planing alone, but following surgery, bacterial populations were reduced and consisted primarily of aerobic or facultative cocci and only one detectable gram-negative anaerobic rod species. Since the composition of the sulcular microflora in microswine with naturally-occurring periodontitis is analogous to that of humans, these animals appear to be an appropriate model for the study of the pathogenesis of periodontal disease.

Detail Summary Sheet

Date: 18 Sep 90 Prot No.: 89-19		Status: Completed
Title: An Evaluation of the Intracanal Temperatures Generated by Injected Thermoplasticized Gutta-Percha		
Start Date: Apr 89		Est Comp Date:
Principal Investigator(s) Dennis L. Donley, LTC, DC		Facility: Tingay Dental Clinic
Dept/Svc: Dental Activity		Associate Investigators: R. Norman Weller, COL, DC James C. Kulild, LTC, DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate time vs temperature ranges of a high-heat thermoplasticized gutta-percha obturation technique.

Technical Approach: Using a research model consisting of an extracted human tooth embedded in a clear resin block with 16 thermocouples attached, warm gutta-percha is injected and a time vs temperature graph is generated using an AIM---7---Input Module.

Progress: An in vitro computerized temperature measurement system was developed to measure intracanal temperatures produced by different heated gutta-percha obturation techniques. The temperatures produced by low- and high-temperature thermoplasticized injectable gutta-percha systems were recorded and compared in this investigation. The mean intrachamber temperature of the Obtura syringe was 178.68°C. The mean temperature of the Ultrafil hjeater was 93.06°C. The mean temperature of the extruded gutta percha was 137.81°V from the Obtura syringe and 62.88%C from the ultrafil cannule. The intracanal temperature of the gutta-percha recorded for both systems indicated that the gutta-percha colls rapidly after injection into the canal.

Detail Summary Sheet

Date: 18 Sep 90 Prot No.: 89-20		Status: Completed
Title: Replication of the Root Canal System: A Comparison of Three Obturation Techniques		
Start Date: Apr 89		Est Comp Date:
Principal Investigator(s) Cheryl S. Budd, MAJ, DC		Facility: Tingay Dental Clinic
Dept/Svc: Denatal Activity		Associate Investigators: R. Norman Weller, COL, DC James C. Kulild, LTC, DC
Key Words: Obturation, Endodontics		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the warm vertical, the warm lateral, and the traditional lateral condensation techniques. Replication of anatomical variations within the root canal and the homogeneity of the filling material will be evaluated.

Technical Approach: Twenty replications each of seven obturation techniques have been completed in vitro in a natural tooth embedded in clear acrylic resin. This resin model is cut in half such that the two halves can be separated allowing the removal of the obturated material. The obturated material is then photographed using a stereomicroscope.

Progress: A new model system was developed to more closely simulate the clinical environment. All obturations were performed in this same model which allowed direct comparisons between the different techniques. The resultant mass of gutta-percha was visually examined and graded for each obturation. Statistical analysis of the results indicated that both thermoplasticized injectable techniques were significantly better than lateral condensation. There was no significant difference between either of the thermoplastic obturation techniques.

Detail Summary Sheet

Date: 26 Oct 90	Prot No.: 89-21	Status: Completed
Title: Spreader and in vitro Intracanal Temperature Measurement Using a Warm Lateral Condensation Technique		
Start Date: Apr 89		Est Comp Date:
Principal Investigator(s) Joseph J. Jurcak, MAJ, DC		Facility: Tingay Dental Clinic
Dept/Svc: Dental Activity		Associate Investigators: R. Norman Weller, COL, DC James C. Kulild, LTC, DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To quantitatively determine the temperatures generated by the Touch 'n Heat endodontic spreader and also the temperature of the gutta-percha filling material inside the canal of a natural tooth at the various power settings.

Technical Approach: This study is designed to evaluate the temperature inside a natural tooth during obturation utilizing gutta-percha and a heated endodontic spreader, Touch-n-Heat. The Touch-n-Heat has 10 power settings and the heat generated at each setting will be measured.

Progress: In vitro intracanal temperatures were measured during warm lateral condensation of gutta-percha. A new model system was developed that allowed repeated obturations on the same tooth throughout the investigation. Obturations were performed with an electrically controlled heated spreader. Temperatures were recorded to 2 decimal places C by 16 intracanal thermocouples connected to a computerized measurement system. The highest intracanal temperature recorded during warm lateral condensation was 114.51'C. Mean temperature changes ranged from 8.18'C to 65.05'C. The spreader was not uniformly heated throughout its entire length. The hottest point on the spreader was 5mm from the tip.

Detail Summary Sheet

Date: 15 Oct 90 Prot No.: 89-22		Status: Completed
Title: A Study of the Subgingival Microflora of HIV+ Males.		
Start Date: Apr 89		Est Comp Date:
Principal Investigator(s) George K. Bumgardner, MAJ, DC		Facility: Tingay Dental Clinic
Dept/Svc: Dental Activity		Associate Investigators: David K. Turgeon, MAJ, MS Scott L. Strong, LTC, DC Michael J. Scheidt, COL, DC Robert B. O'Neal, COL, DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the oral microflora of HIV+ male patients with and without adult periodontitis with the microbial flora of systemically healthy males with and without periodontitis.

Technical Approach: Subjects included a control group of 13 healthy patients without periodontitis (HIV-, P-), 6 patients with periodontitis (HIV-, P+), 12 HIV+ patients without periodontitis (HIV+, P-), and 6 HIV+ patients with periodontitis (HIV+, P+). Subgingival samples for microbiologic studies were obtained from the mesiobuccal surface of the two teeth exhibiting the deepest radiographic osseous defect as determined by panorex. paper point samples were dispersed in prereduced media, plated on selective and non-selective media and grown in aerobic, anaerobic and capnophilic atmospheres.

Progress: Results revealed that the predominant cultivable microorganisms in HIV-, P-group were alpha streptococci, B. buccalis, B. intermedius, B. oralis, F. necrophorum, F. varium, and Staphylococcus species. The HIV-, P+ group demonstrated aerobic gram negative rods, alpha streptococci, Baccilus species, Enterobacter aerogenes, F. nucleatum, Fusobacterium species, aerobic gram negative rods, K. pneumonia, Pseudomonas fluorescence and Staphylococcus species. The HIV+, P+ group demonstrated alpha streptococci, E. cloacae, F. nucleatum, F. varium, D. pneumoniae, Staphylococcus species, and yeasts. Our study revealed no consistent difference between the microorganisms found in patients regardless of whether or not they were infected with the HIV virus. The data suggests that the microorganisms associated with HIV associated periodontitis is complex with high numbers of bacteria but not the classical pathogenic bacteria by today's definition. Clearly host-response is involved but our data does not suggest introduction of new microorganisms, rather more of the same microorganisms found before.

Detail Summary Sheet

Date: 15 Oct 90 Prot No.: 89-23		Status: Completed
Title: The Penetration of Lavage Solution into the Periodontal Pocket During Ultrasonic Instrumentation		
Start Date: Apr 89		Est Comp Date:
Principal Investigator(s) Gregory Nosal, LTC, DC		Facility: Tingay Dental Clinic
Dept/Svc: Dental Activity		Associate Investigators: Michael J. Scheidt, COL, DC Robert O'Neal, COL, DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 90 Review Results Continue

Study Objective: To evaluate the penetration depth of the water coolant during use of the Cavitron ultrasonic device.

Technical Approach: An ultrasonic Cavitron tip, employing a dye colored liquid coolant, is placed to the apical extent of the periodontal pocket in teeth that have been treatment planned for extraction. The tooth is extracted and the apical extent of coolant penetration is determined by noting the stain pattern on the tooth.

Progress: The results indicated dye stained water coolant along the full extent of the probe tip's penetration path. The dispersion of the dye colored stain was localized to the area of the ultrasonic probe with very little lateral disperson. The ultrasonic instrument may be an effective system to mechanically remove plaque and calculus at the same time as delivering a chemotherapeutic agent. The limited dispersion of the liquid dye would indicate that chemical plaque with this delivery system is dependent upon thorough debridement with the instrument such that all affected surfaces are instrumented.

Detail Summary Sheet

Date: 15 Oct 90 Prot No.: 89-24		Status: Completed
Title: An in vivo Study of Dentin Sensitivity: The Relation of Dentin Sensitivity and the Patency of Dentin Tubules		
Start Date: Apr 89		Est Comp Date:
Principal Investigator(s) Michael F. Cuenin, MAJ, DC		Facility: Tingay Dental Clinic
Dept/Svc: Dental Activity		Associate Investigators: Michael J. Scheidt, COL, DC Robert B. O'Neal, COL, DC Scott L. Strong, LTC, DC David H. Pashley, D.M.D., PhD
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results Mar 90 Continue

Study Objective: To acquire a better understanding of the cause of sensitive teeth, specifically dentin sensitivity. The scanning electron microscope will be used to evaluate dentin tubule closure and its relationship to the thermal and tactile response of the tooth.

Technical Approach: Patients treatment planned for the extraction of teeth exhibiting recession are treated as follows: 1) initial sensitivity scored; 2) treatment with EDTA, sensitivity then scores; 3) treatment with either potassium oxalate or sterile saline; sensitivity scores.

Number of subjects enrolled to date: 20
Number of subjects enrolled for the reporting period: 3

Progress: Twelve of the 20 patients (60%) presented with some form of baseline dentin sensitivity in response to the air stimulation. Six of 12 patients had equal or increased sensitivity after treatment with EDTA. Of the remaining 8 "non-sensitive" patients, 1 related sensitivity after treatment with EDTA while 7 related no change in sensation and consistently graded their response as (not sensitive." The resulting 13 "dentin sensitive" patients (12 who presented with somer esponse, and 1 who had sensitivity "induced" with EDTA) constituted the treated patients. Of the 6 dentin sensitive subjects treated with the potassium oxalate solution 4 related no immediate change, 1 related immediate reduction or elimination of dentin sensitivity, and 1 had immediate increased sensitivity. While, of the 7 dentin sensitive subjects treated with the sodium chloride solution all 7 related an immediate reduction or elimination of sensitivity.

Detail Summary Sheet

Date: 16 Oct 90	Prot No.: 89-25	Status: Completed

Title: In vitro Fibroblast Attachment to Chlorhexidine Treated Root Surfaces

Start Date: Apr 89		Est Comp Date:
Principal Investigator(s) Charles D. Alleyn, MAJ, DC		Facility: Tingay Dental Clinic
Dept/Svc: Dental Activity		Associate Investigators: James C. McPherson III, PhD Scott L. Strong, LTC, DC Robert O'Neal, COL, DC Michael J. Scheidt, COL, DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether fibroblast attachment is altered on chlorhexidine treated tooth surfaces in vitro.

Technical Approach: Extracted teeth were collected, cleaned and sectioned. The surface area of each tooth root section was measured. The root sections were divided into groups of ten. One control group and one group treated with chlorhexidine for three minutes were allowed to incubate with human gingival fibroblasts. At 1, 2, 4, 6, and 8 hrs of incubation time the tooth roots were removed and the attached fibroblasts counted. In an additional experiment, groups of ten root sections were incubated for 30 sec, 90 sec, or 3 min with chlorhexidine and fibroblasts allowed to attach for one hour.

Progress: There was a reduction in the number of fibroblast attachment/mm squared of root surface in all 3 experimental groups relative to the control group. The difference between the experimental and the control groups is statistically significant at the $p<0.001$ level. The difference between the experimental groups at one hour is not statistically significant. In other words chlorhexidine treatment of dentin ships resulted in a statistically significant reduction in fibroblast attachment with a one hour incubation time but it did not matter if the dentin chips were exposed to chlorhexidine for 30 seconds, 90 seconds, or 3 minutes. In the second experiment dentin chips which had been exposed to chlorhexidine for 3 minutes were incubated with the fibroblasts for 2, 4, 6, or 8 hours. The chlorhexidine treatment resulted in a statistically ($p<0.001$) significant reduction in fibroblast attachment relative to the controls at all time periods. However the within groups differences were not statistically significant i.e. time of incubation with fibroblasts had no effect on attachment. In other words chlorhexidine resulted in a statistically significant reduction in fibroblast attachment relative to the controls irrespective of time of incubation with fibroblasts.

Detail Summary Sheet

Date: 16 Oct 90 Prot No.: 89-34		Status: Completed
Title: The Relationship Between the Frankfort-Mandibular Angle and Lateral Disclusion Patterns.		
Start Date: Jul 89		Est Comp Date: May 90
Principal Investigator(s) Rodger A. Lawton, MAJ, DC		Facility: Dental Activity
Dept/Svc: Tingay Dental Clinic		Associate Investigators: Marion J. Edge, COL, DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To examine the relationship between a subject's facial structure and their lateral disclusion scheme.

Technical Approach: Computer analysis of the subject's occlusion are correlated with external measurements of their facial profile. Manpower used in the study has been the investigator and his dental assistant. Funding in the past fiscal year has been about $3000 for purchase of the analyser and sensors.

Number of subjects enrolled: 47

Progress: A statistically significant correlation was found for the relationship between a person's Frankfort-mandibular plane angle and both their right and left lateral disclusion patterns. As a person tends toward the higher end of the FMA range (>30 degrees), they are more likely to exhibit a posterior group function. When restoring a patient whose lateral disclusion pattern will be involved, the patient's FMA should be determined. Low and middle angle patients can be comfortable restored with a canine discluded articulation. However, the likelihood is that the high angle patient probably would have exhibited a group function pattern had their occlusion been undisturbed by dental disease. Restoring this patient with a group function should allow for a more physiologically harmonious occlusal relationship.

Detail Summary Sheet

Date: 10 Oct 90 Prot No.: 89-42		Status: Ongoing
Title: The Effect of Titanium Implant Surface Roughness on Plaque Accumulation.		
Start Date:		Est Comp Date:
Principal Investigator(s) Judith McCollum, MAJ, DC		Facility: Dental Activity
Dept/Svc: Tingay Dental Clinic/Clinical Investigation		Associate Investigators: Robert B. O'Neal, COL, DC William A. Brennan, COL, DC Thomas E. Van Dyke, DDS Jack A. Horner
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate in vitro the surface texture of titanium implant abutments after exposure to plastic scalers, an air-powder abrasive system, and rubber cup polishing with a fine abrasive past; and to compare plaque accumulation in humans on abutments treated with the above prophylaxis methods.

Technical Approach:

Progress: In vitro protion completed for 16 sets of abutments. In vivo portion completed for 10 patients.

Detail Summary Sheet

Date: 12 Sep 90 Prot No.: 89-43		Status: Ongoing
Title: The Effect of Pluronic Polyols on the Attachment and Growth of Human Gingival Fibroblasts to Glass and Human Tooth Root Surfaces in vitro		
Start Date:		Est Comp Date:
Principal Investigator(s) Steven D. Hokett, MAJ, DC		Facility: Dental Activity
Dept/Svc: Tingay Dental Clinic/Clinical Investigation		Associate Investigators: Robert B. O'Neal, COL, DC William A. Brennan, COL, DC Scott L. Strong, LTC, DC James C. McPherson, III, PhD Thomas E. Van Dyke, DDS Royce R. Runner, ASCP
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether human gingival fibroblast attachment and growth is altered in tissue culture media containing Pluronic polyols in vitro to a glass surface and human tooth root surfaces.

Technical Approach:

Progress: 1. Unerupted third molars collected from Oral Surgery, DDEAMC.

2. Dentin sections prepared and surface area measured using standard tin foil. (121 samples prepared); standard curve for foil weights determined.

3. Human gingival fibroblasts (HGFs) are presently being used in pilot studies to determine laboratory technique for a colorimetric cell-counting assay utilizing methylene blue.

4. The optimum concentrations [Mm osmolarity] of Pluronic F-68/F-127 and standard curves are being determined at present. These will be used during the final phases of the experiment.

Detail Summary Sheet

Date: 10 Oct 90 Prot No.: 89-44 Status: Ongoing

Title: The Effect of Non-ionic Surfactants on Wound Healing in Rats

Start Date:		Est Comp Date:
Principal Investigator(s) Brian D. Fitzpatrick, MAJ, DC		Facility: Dental Activity
Dept/Svc: Tingay Dental Clinic/Clinical Investigation		Associate Investigators: Robert B. O'Neal, COL, DC Scott L. Strong, LTC, DC James C. McPherson, III, PhD Thomas E. Van Dyke, DDS Royce R. Runner, ASCP
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the effect of non-ionic surfactants on wound healing in rats.

Technical Approach:

Progress: Data for animals using pluronic polyol F-68 and control (normal saline) has been obtained. Route of administration was intraperitoneal (IP). Data for animals using IP F-127 remains to be done.

Detail Summary Sheet

Date: 10 Oct 90 Prot No.: 89-45		Status: Ongoing
Title: Effects of Microencapsulated Antibiotics on the Microorganisms Present in Periodontitis of the Micro Swine		
Start Date:		Est Comp Date:
Principal Investigator(s) Stephen J. Awe, MAJ, DC		Facility: Dental Activity
Dept/Svc: Tingay Dental Clinic/Clinical Investigation		Associate Investigators: Scott L. Strong, LTC, DC Robert B. O'Neal, COL, MC David K. Turgeon, CPT, MS William A. Brennan, COL,DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the effects of microencapsulated antibiotics on the microorganisms preent in periodontitis in the micro swine.

Technical Approach:

Progress: Antibiotics for study received 10 Sep 90. Culture media for micro is on order.

Detail Summary Sheet

Date: 9 Oct 90	Prot No.: 90-3	Status: Ongoing

Title: The Effect of Polytetrafluorethylene (PTFE) Membranes and Polylactic Acid (PLA)/Polyglycolic Acid (PGA) Membranes in Guided Tissue Regeneration (GTR) in Micro Swine.

Start Date:		Est Comp Date:
Principal Investigator(s) George V. Millett III, MAJ, DC		Facility: Tingay Dental Clinic
Dept/Svc: Dental Activity		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: The use of guided tissue regeneration in an animal model, involving induced periodontal defects, will be evaluated by the comparative effectiveness of two types of materials used in guided tissue regeneration in the treatment of periodontal disease.

Technical Approach:

Progress: All surgeries have been performed to place the filters, the appropriate time has elapsed and the filters removed. Unfortunately, it is apparent that the pig may not be a good model for this particular research. The buccal muscle attachment is too high in the ridge and the buccal mucogingival flaps are virtually impossible to retain around the teeth. Subsequently the filters were uncovered prematurely and all but one was lost. The protocol is being continued.

Detail Summary Sheet

Date:	Prot No.: 90-4	Status: Ongoing
Title: Surgical Treatment of Induced Peri-implantitis in the Micro Swine: Clinical and Histological Analysis.		
Start Date:		Est Comp Date:
Principal Investigator(s) Gurbhajan Singh, MAJ, DC		Facility: Tingay Dental Clinic
Dept/Svc: Dental Activity		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the potential of a new membrane technique, based on guided tissue regeneration for bone healing.

Technical Approach:

Progress: Only the histological analysis of the samples is left to do.

Detail Summary Sheet

Date: 9 Oct 90	Prot No.: 90-17	Status: Ongoing
Title: Root Canal Shape of the Mandibular First Premolar.		

Start Date: May 90	Est Comp Date:
Principal Investigator(s) Michael K. Baisden, MAJ, DC	Facility: Tingay Dental Clinic
Dept/Svc: Endodontic	Associate Investigators: R. Norman Weller, COL, DC James C. Kulild, COL, DC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the shape of the root canal system of the mandibular first premolar and also record the percentage of multiple canal systems and variant anatomy which may be found.

Technical Approach: Each tooth was sectioned with a thin separating disk at 3 mm intervals from the apex to CEJ. Specimans were then placed in 5.25% NaCl to remove organic debris from canal(s). Then each speciman was rinsed with tap water, mounted and photographed with the stereomicroscope. Slides/sections were then mounted and evaluated.

Progress: A total of 106 mandibular first premolars have been sectioned, photographed, mounted, and evaluated. Data was compiled and submitted for grading.

Detail Summary Sheet

Date: 9 Oct 90 Prot No.: 90-18		Status: Ongoing
Title: The Effect of Root Canal Smear Layer Removal on the Diffusability of Calcium hydroxide.		
Start Date: May 90		Est Comp Date:
Principal Investigator(s) Keith H. Foster, MAJ, DC		Facility: Tingay Dental Clinic
Dept/Svc: Endodontic		Associate Investigators: R. Norman Weller, COL, DC James C. Kulild, COL, DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To quantitatively determine diffusion of hydroxyl ions through root dentin to an external medium and the effect of the presence or absence of smear layer on that diffusion.

Technical Approach: Extracted teeth instrumented to size 50 were divided into four groups. Group 1 had final irrigation with normal saline, no Ca(OH)2 placed. Group 2 final irrigation 10 cc EDIA, then 5.2% NaOCl 10cc, no Ca(OOH)2 placed. Group 3 final irrigation 20 cc 5.2% NaOCl, Ca(OH)2 placed. Group 4 final irrigation 10 cc EDTA, then 10 cc 5.2% NaOCl, Ca(OH)2 placed. All teeth apices and access preps sealed, placed in vials with 10 cc normal saline. $(OH)1^{-1}$ measured indirectly by pH meter and Ca^{++} ions measured directly at 1,3,5,7 days at which time external 3x3x1 mm defect made on teeth. OH^{-1} and Ca^{++} again read at 1,3,&7 days.

Progress: As of September 1990, experiment as designed above has been completed. Adjunctive studies are currently underway to explain/substantiate findings.

Detail Summary Sheet

Date: 9 Oct 90 Prot No.: 90-19		Status: Ongoing
Title: The Effect of Mechanical Versus Thermal Removal of Gutta-Percha on the Quality of the Apical Seal Following Post Space Preparation		
Start Date: May 90		Est Comp Date: Dec 90
Principal Investigator(s) Randall S. Hiltner, MAJ, DC		Facility: Tingay Dental Clinic
Dept/Svc: Endodontic		Associate Investigators: R. Norman Weller, COL, DC James C. Kulild, COL, DC
Key Words: Apical seal, dye leakage, post preparation		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the effects on the apical seal by two new methods of gutta-percha removal for post space preparation.

Technical Approach: Eighty-six extracted teeth were sectioned and instrumented to a fixed working length. The teeth will be obturated with gutta-percha and the sealer allowed to set for at least one week while stored at physiological temperature. All but 5mm of the gutta-percha will be removed by one of four different techniques and the quality of the apical seal evaluated by dye leakage.

Progress: Eighty-six extracted human canines have been obtained and sectioned at the cementoenamel junction. The apical foramen was determined for each tooth by passing a #10 file through the apex and visually determining the point of exit. Working length was established 1mm short of the apical foramen and each tooth was reduced by coronal grinding until a fixed length of 15mm was established. All teeth were instrumented to a #40 file and step back filing performed to a size 50. An incubator was obtained from Clinical Investigation to use for storage of obturated teeth. COL Kulild and I discussed the study with Dr. Swindisky and determined the statistical approach best suited for this study would be to limit variables and degrees of error by using only one operator to measure dye leakage. Supplies for gutta-percha obturation and instruments for removal have been procured. To date, thirty-six of the teeth have been obturated. Radiographs have been taken on each tooth to confirm proper canal fill.

Detail Summary Sheet

Date: 9 Oct 90 Prot No.: 90-30 Status: Ongoing

Title: The Bond Strength of Opaqued, Silicoated Metal.

Start Date: Jul 90	Est Comp Date: Mar 91
Principal Investigator(s) Thomas B. Lefler, MAJ, DC	Facility: Dental Activity
Dept/Svc: Tingay Dental Clinic	Associate Investigators: Edge MJ, COL, DC Krantz, WA, COL, DC Adrian E, COL, DC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To test bond strength of silicoated, opaqued metal and compare to bond strength of beaded, opaqued , and beaded metal.

Technical Approach: Metal patterns are being cast out of symphony metal. Acrylic resin is processed to these patterns. The resin is then sheared off with an Ingstrom. Eight ounces of symphony metal were purchased last year. Ten patterns have been made with this metal. 22 dwt of the metal was used to make these. I estimate that I will need another 120dwt of the metal. I need to make at least 50 more patterns. I should have sufficient metal to finish. I will need to order more plastic patterns to use (2 packages at 9.50 ea).

Progress: I have completed the pilot study. This was done to determine if my experimental design would work in the Ingstrom. The design proved to be good. The only problem I had with the pilot study was the bond strength of the silicoated specimens was less than what it was projected to be. This could have been due to either an error in my technique or bad chemical in the silicoater. I am redoing five silicoated specimens to see if my first set of numbers was correct. After completing these, then I will proceed with the fabrication of the rest of the test patterns.

Detail Summary Sheet

Date: 10 Sep 90 Prot No.: 88-7		Status: Ongoing
Title: Relationship of Maternal Body Fat Composition to Pregnancy Outcome.		
Start Date:		Est Comp Date:
Principal Investigator(s) Ronald J. Edwards, MD, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Family Practice		Associate Investigators: Wiley Smith, MD, MAJ, MC
Key Words		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: This study will describe the relationship of maternal prenatal nutritional status as reflected by maternal body fat composition, to specific outcome variables (maternal hypertension, maternal height and weight, increased bleeding during labor and delivery, preeclampsia, excess pregnancy weight gain, prolonged labor, birth weight, fasting blood sugar at onset of pregnancy, O'Sullivan value at 28 weeks and maternal blood pressure). Prenatal weight gain has long been a parameter followed during adequate monitoring of pregnancy, but many variables join to determine overall weight gain (ie, fetal size, volume of amniotic fluid, maternal fluid retention). Change in body fat composition during the course of pregnancy has not been well described in the literature; this definition is anticipated to add to the true descriptive picture of adipose tissue content of the pregnant woman.

Technical Approach:

1. Summary of experimental design: Body fat content is an important indicator of nutritional status in health and disease. The most reliable measurement of body fat is the underwater weighing technique because it generally eliminates most of the measurement errors and is felt to come closest to telling the truth about the true percentage of the body composition made up by fat tissue. However, it is cumbersome, generally unavailable, and for some studies and subjects, impractical or impossible. Other methods of body fat measurement (BFM) that have been investigated include anthropometry, isotope dilution, ultrasound, computed tomography, magnetic resonance imaging, and neutron activation. Each of these methods has interesting possibilities or advantages but most are limited by the cost or availability of the equipment or by the invasive nature of the testing procedure leaving anthropometry and electrical impedence as the available, affordable and usable (ie, no invasive threat to the mother or fetus) modes in the current study. (Bray, Contemporary Nutrition.)

All patients enrolled for obstetrical care at the Family Practice Clinic at DDEAMC who are willing to participate in the study are included as subjects, until 50 subjects are identified. These subjects have both skin caliper and electroplythesmography (EPG) measurements made at the time of their first

88-7 - Continued

evaluation. At each month thereafter during their pregnancy, their body content is to be analyzed by the EPG method. At the postpartum visit at 6 weeks and 6 months, both skin caliper and EPG measurements will again be made. Additional data to be gathered on each subject includes height, weight, birth weight of the baby, single or multiple birth, O'Sullivan scores (at the standard 16 and 36 week milestones), initial fasting blood sugar, blood pressure at each body fat measurement interval, presence of abnormal bleeding during labor, length of labor stages (1,2,3,4), the presence of preeclampsia/eclampsia, and the method of feeding of the newborn. All of these variables are already being measured by the standard obstetrical care protocol and so involve no additional testing of the subject.

Longitudinal progress of body fat is calculated through the course of the pregnancies, using multiple analysis of variance techniques to consider the variables named above. Adjustments will be made for age, parity, and prepregnancy body fat content. A separate analysis will be made of the rate and extent of return to prepregnancy body fats.

1. Manpower: The only manpower employed (available) has been the investigator and the RN. Some administrative assistance has also been available and the ordinary nursing care used to gather routine obstetrical data has been in place.

3. Funding: Only office supplies and data gathering time and minimal computer time have been expended.

Number of subjects enrolled to date: 43
Number of subjects enrolled for reporting period: 0

No adverse reactions have been recognized.

Progress: No further data collection has occurred. Data analysis has proven difficult due to the missing data points and the need for repeated measures analysis. Presently working with Mr. Davis at MCG research division on analysis.

Date: 10 Oct 90	Prot No.: 89-1	Status: Completed

Title: An Evaluation of Buspirone for the Treatment of the Tobacco Withdrawal Syndrome.

Start Date: Jul 89		Est Comp Date:
Principal Investigator(s) Mark D. Robinson, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Family Practice		Associate Investigators: Wiley A. Smith, MD, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To examine whether buspirone will decrease the severity and/or the frequency of tobacco withdrawal symptoms in patients with tobacco dependence disorder.

Technical Approach: Tobacco withdrawal symptoms are a major obstacle to smoking cessation in nicotine dependent smokers. Uncontrolled clinical trials have reported favorable effects of buspirone, a new non-benzodiazepine anxiolytic, on nicotine withdrawal. This was a randomized, prospective, double-blind clinical trial of buspirone for the treatment of nicotine withdrawal symptoms.

Number of subjects enrolled to date: 54
Number of subjects enrolled for reporting period: 20

No adverse reactions to date.

Progress: We recruited cigarette smokers from a population of active duty and retired military health beneficiaries. Study eligibility required that smokers meet DSM IIIR criteria for nicotine withdrawal on a previous quit attempt. Fifty-four otherwise healthy smokers were randomly assigned to treatment with orally administered buspirone or placebo in a double-blind fashion. All smokers were titrated to the target dose of 30mg per day over a ten day period and continued on this dose for the remainder of the three week premedication period. Smokers then abruptly discontinued smoking on the quit date without prior tapering. A validated tobacco withdrawal scale and the Spielberger state-anxiety scale were administered at baseline, on the quit date, and then at 24 hours, 48 hours, one week, and two weeks after abrupt cessation. Random urine cotinine and expired carbon monoxide were sampled at each visit to confirm abstinence.

Twenty-seven patients received buspirone and 27 received placebo. There were no significant baseline differences between groups on age, sex distribution, cigarettes smoke/day, years smoked, prior quit attempts, expired carbon monoxide, urine cotinine, or Fagerstrom Tolerance scores (alpha=.05). Three

smokers (one on buspirone, two on placebo) dropped out of the protocol prior to the quit date. Two of these (one from each group) experienced intolerable adverse effects. Repeated measures ANOVA for total withdrawal score, Spielberger state-anxiety, as well as for the withdrawal symptoms of craving, irritability, anxiety, difficulty concentrating, restlessness, hunger, and pulse rate revealed no significant effect of buspirone over placebo (alpha=0.05). Significant effects over time for all of these withdrawal symptoms were observed in each group ($p<0.0001$). Relapse rates at each follow-up visit were not significantly different between groups. The two-week abstinence rates were 48% for placebo and 59% for buspirone ($p=0.648$).

We conclude that buspirone offered no advantage over placebo for nicotine withdrawal symptoms for these heavy smokers. Significant nicotine withdrawal occurred in each group. The study was designed to be able to detect moderately large treatment effects. Although the sample size is modest, the study had adequate power to detect a clinically meaningful effect in this population of smokers. Additional studies will be needed to determine whether buspirone will have any effect on long term abstinence rates.

Detail Summary Sheet

Date: 18 Sep 90 Prot No.: 89-41 Status: Ongoing

Title: Infectious Etiologies for Inflammatory PAP Smears.

Start Date: 1 Aug 90		Est Comp Date: 1 Aug 91
Principal Investigator(s) David D. Ellis, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Family Practice		Associate Investigators: David L. Maness MD, MAJ, MC Bettie B. Wagstaff, MD, LTC, MC Diane R. Sommer, MD, CPT, MC Kathy Powers, MD, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate patients with inflammation on PAP smear for infectious etiologies and identify the most common agents.

Technical Approach:
(1) Summary of experimental design - Prevalence study.
(2) Manpower - Investigators and one nursing staff, cytotechnologist, and pathologist.
(3) Funding - None.
(4) Number of subjects enrolled to date - 202.
(5) Number of subjects enrolled for reporting period - 202.
(6) Significant adverse reactions - None.

Progress: (1) Results:
(a) 60% - No demonstrable infectious etiology on initial exam.
(b) 20% - Candida vaginitis.
(c) 15% - Bacterial vaginitis.
(d) 2% - Human papilloma virus as per colposcopy. (This is incomplete data, as all colposcopies have not been completed.)
(e) 0% - Chlamydia trachomatis.
(f) 0% - Gonorrhea.
(g) 3% - Herpes simplex.

(2) Current stage of data collected:
(a) All patients have been enrolled.
(b) Repeat PAP smears are being completed and will be finalized in Dec 1990.
(c) Repeat PAP smears with inflammation will go to Gynecology Clinic for colposcopy. This data will be collected, recorded, and completed by Feb 1990.

Detail Summary Sheet

Date: 10 Sep 90 Prot No.: 90-6		Status: Completed
Title: Postpartum Blues and Associated Factors in a Military Population.		
Start Date: Oct 89		Est Comp Date:
Principal Investigator(s) Bruce A. Leibert, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Family Practice		Associate Investigators: Robert M.L. Johnson, DO, LTC, MC
Key Words: Postpartum Blues		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the incidence of Postpartum Blues (PPB) in our population and to identify associated factors.

Technical Approach: The investigator conducted a 35-question scripted interview, the women completed Barnett's Life Events Scale for Obstetric Groups, and the obstetric chart was reviewed for prenatal, perinatal, and postnatal complications.

Number of subjects enrolled: 60.

Progress: Fifteen of our sixty subjects experienced PPB during the first ten days after delivery. Age, parity, prenatal classes, labor experience and separation from the spouse did not appear to be associated with the blues. Infant feeding difficulties did increase the risk of development of PPB in this population. This factor could be addressed by creating educational programs aimed at teaching proper feeding techniques. These programs will need to be studied for effectiveness in improving maternal-infant bonding and decreasing the incidence of PPB.

The definition of PPB needs to be standardized. The majority of research on PPB has involved self-reporting questionnaires and interviews. Future studies should include family members and clinical observer assessments. If this data correlates with the results of self-reporting tolls, a set of reliable and useful diagnostic criteria can be constructed.

Detail Summary Sheet

Date: 10 Sep 90 Prot No.: 90-9		Status: Completed
Title: Changes in Nutritional Status and Physical Conditioning During Residency.		
Start Date: Jan 90		Est Comp Date:
Principal Investigator(s) Daniel E. Walker, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Family Practice		Associate Investigators: Ronald Edwards, MD, LTC, MC
Key Words: Residency, Nutrition		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To track several nutritional parameters during a family practice internship in 10 house staff. Hope to see if there are measurable changes associated with the rigors of the PGY1 year.

Technical Approach: Obtain quarterly lab tests, exercise tolerance and body fat measurements.

Manpower: All work performed by Drs. Walker and Edwards.

Funding: Per discussion with LTC Bolton, Pathology MS officer, the lab tests, needles, and tubes would be carried on routine funding and would not require special funding.

Number of subjects enrolled: 10 Family Practice Interns - Class of 1989-1990.

No adverse reactions.

Progress: Data collection complete. Currently planning to meet with stat analysis expert at MCG to analyze results. Initial review shows lifestyle changes as per questionnaire but no measurable laboratory changes.

Detail Summary Sheet

Date: 13 Aug 90	Prot No.: 90-10	Status: Terminate

Efficacy of Sustained Release Diltiazem in Treating Hypertensives.

Start Date:		Est Comp Date:
Principal Investigator(s) Kenneth L. Farmer, Jr., MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Family Practice		Associate Investigators: Cindy C. Wilson, PhD, USUHS
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To study the potential effectiveness of diltiazem sustained release in adult patients with mild to moderate high blood pressure.

Technical Approach:

Progress: Study disapproved by HSC, terminate.

Detail Summary Sheet

Date: 8 Nov 90 Prot No.: 90-28		Status: Completed
Title: Assessment of Orthostatic Blood Pressure and Heart Rate Changes in Young, Normovolemic Adults		
Start Date: Jun 90		Est Comp Date:
Principal Investigator(s) Brent C. Nimeth, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Family Practice		Associate Investigators: Michael C. Foster, MD, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective:

Technical Approach: Male and female subjects, ages 18 to 25 will lie supine for 7 minutes while heart rate and blood pressure measurements are recorded using an automatic non-invasive blood pressure monitor. Measurements will be recorded at 1, 2, 3, 5, and 7 minutes. The subjects will then stand and measurements repeated at the same time intervals.

Number of subjects enrolled to date: 40

Progress: Forty subjects, ages 18-25, 25 males and 15 females, meeting criteria classifying them as normovolemic participated in the study. Heart rate and blood pressure were measured at various intervals supine and standing. There was no statistical difference in systolic blood pressure or heart rate supine or after 2 minutes standing. This suggests the optimal time intervals in performing a tilt test are waiting at least 1 minute supine and minutes after standing before recording vital signs. Forty percent of the study population had a heart rate rise of greater than or equal to 20 beats per minute, classifying them as "tile positive." A positive tilt test is very nonspecific in this group of subjects.

Detail Summary Sheet

Date: 23 Oct 90	Prot No.: 90-39	Status: Ongoing

Title: Adverse Events Associated with the Influenze Vaccine.

Start Date:		Est Comp Date:
Principal Investigator(s) Barton G. Williams, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine, Family Practice, Preventive Medicine		Associate Investigators: Dale Carroll, MD, LTC, MC
Key Words:		David R. Haburchak, MD, COL, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective:

Technical Approach:

Progress: Local approval in Sep 90, no reportable data.

Detail Summary Sheet

Date: 10 Oct 90 Prot No.: 78-38		Status: Ongoing
Title: Efficacy of Immunotherapy for Systemic Allergic Reaction to Imported Fire Ant Stings. Human Immunologic Reactivity to Fire Ant Antigens. BB IND 1452, Part II, III		
Start Date: Feb 78		Est Comp Date:
Principal Investigator(s) Chitra Kutiala, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Immunology		Associate Investigators: Robert B. Rhoades, MD, Medical College of Georgia
Key Words:		Chester T. Stafford, MD, Medical College of Georgia
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 89 Review Results Continue

Study Objectives: a. To ascertain the relative efficacy of immunotherapy with whole body extracts and venom compared to placebo in the treatment of systemic hypersensitivity to stings of the imported fire ant.

b. To ascertain the natural history of imported fire ant hypersensitivity and to identify possible subgroups who may undergo spontaneous desensitization and not require immunotherapy.

Technical Approach: Experimental design: Patients found to be allergic to fire ants by history and laboratory parameters will be placed on placebo, whole body extract or venom. After approximately eight weeks, patients will be hospitalized for repeat laboratory parameters and challenge to fire ant bite. Depending on outcome, adjustment of treatment will be done accordingly.

Number of subjects enrolled to date: 7
Number of subjects enrolled for reporting period: 0

Progress: No reportable data available.

Detail Summary Sheet

Date: 10 Oct 90	Prot No.: 83-22	Status: Ongoing
Title: Use of Isotretinoin in Prevention of Basal Cell Carcinoma		

Start Date: Feb 85	Est Comp Date:
Principal Investigator(s) Marshall A. Guill, MD, COL, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Dermatology	Associate Investigators: John R. Cook, MD, COL, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Jan 90 Review Results Continue

Study Objective: To evaluate the effectiveness of low dosage levels of Isotretinoin in reducing the incidence of basal cell carcinomas in a high risk population. To examine possible side effects associated with long term administration of low doses of Isotretinoin.

Technical Approach: Patients with two or more basal cell carcinomas (BCC) in the past five years are eligible for inclusion in the study. They must be between the ages of 40 and 75 and incapable of bearing children. After a thorough physical examination, including basic laboratory data, participants are randomized to either the treatment group or the placebo group. The medication is provided by the National Cancer Institute and is double-blinded. Participants take medication for 36 months, continuing to be followed for the following 24 months for a total of 60 months in the study.

Funding: A total of $58,804 was provided this fiscal year by NCI.

Number of subjects enrolled to date: 132

Progress: Our initially randomized patients have all completed the medication phase of the study. There have been no new signs of DISH or severe lab abnormalities. Several patients have noted an increase in recurrences of basal cell carcinomas since stopping the medication. Very few patients who have completed more than 48 months in the study have had no basal cells since the two week visit.

We continue to follow the randomized patients every six months at Hunter Army Air Field in Savannah, Georgia.

There are 55 patients who have finished the five year program and most have chosen to return for post study follow ups. We will continue to send pathology reports and slides to NCI through the end of the study.

The ancillary support from laboratory, x-ray and pathology departments at DDEAMC, Fort MacPherson, Hunter Army Air Field and Fort Stewart continues to be excellent.

83-22 - Continued

The three year extension of the study will continue through September 1991. The NCI has requested that patients who did not receive a total of three x-rays during the initial three year period be x-rayed in the next year. This includes about forty patients and an additional $1000 has been allotted for this procedure.

In July of this year, the blind was broken and all the patients were notified by individual letters if they were on the placebo or Isotretinoin. Patients who completed the full five year program were mailed framed certificates of appreciation for their participation. The final consensus meeting of the study group will meet in January 1991 in Bethesda, Maryland. At that time, preliminary findings will be announced and press releases will follow.

There were no adverse reactions while the last few patients remained on the medication.

We continue to have a high rate of compliance and enthusiasm amongst our patients.

Detail Summary Sheet

Date: 24 Oct 90 Prot No.: 87-1		Status: Ongoing
Title: Causes of Transient Myocardial Ischemia in Asymptomatic and Symptomatic Patients with Coronary Artery Disease.		
Start Date:		Est Comp Date:
Principal Investigator(s) George S. Rebecca, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Jan 90 Review Results Continue

Study Objective: To assess the sensitivity of different segments of epicardial coronary arteries in patients using quantitative coronary arteriography and to measure by computer the responses of epicardial coronary arteries.

Technical Approach: Up to now non-specific provocations and severe technical deficiencies have limited the resolutions of pathophysiological events and hindered attempts to find specific causes of ischemia. The proposed aims to answer: 1) The relative importance of physical activity; mental arousal and truly spontaneous events in the genesis of ischemia in normally active patients out of hospital. For this purpose clinical characterization, diaries and frequency modulated Holter monitoring of the electrocardiogram will be performed in well characterized patients; 2) The second aim is to use quantitative angiography, myocardial oxygen demand and incidence of ischemia to study patients at cardiac catheterization in order to examine the initial causes of sequence of events triggering ischemia during maneuvers that are related to events outside the hospital.

Number of subjects enrolled to date: 108
Number of subjects enrolled for reporting period: 8

Progress: Study going well.

Detail Summary Sheet

Date: 24 Oct 90 Prot No.: 88-19		Status: Ongoing
Title: Evaluation of Nitroglycerin Therapy in Patients with Asymptomatic Coronary Artery Disease and Silent Ischemia		
Start Date:		Est Comp Date:
Principal Investigator(s) George S. Rebecca, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Jan 90 Review Results Continue

Study Objective: To determine the effectiveness of Transderm-Nitro in abolishing "silent" ischemia in subjects with documented but asymptomatic coronary artery disease.

Technical Approach: The frequency and duration of ischemic episodes will be measured by analysis of ST segments recorded during ambulatory ECG monitoring. An ischemic event will be defined as horizontal or downsloping ST segment depression lasting for 60 seconds or longer. The depth of the depression must be 1 or more mm from the baseline established by the TP or PR interval as measured 80 msec from the J point. Monitoring will be performed in the lead demonstrating maximum ST depression during exercise testing.

Jackson Foundation Funding: $20,000

Number of subjects enrolled to date: 26
Number of subjects enrolled during reporting period: 18

Progress: Evaluations are continuing.

Detail Summary Sheet

Date: 24 Oct 90 Prot No.: 88-24		Status: Ongoing
Title: Pathophysiology of Coronary Artery Dilatation		
Start Date:		Est Comp Date:
Principal Investigator(s) George S. Rebecca, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic May 90 Review Results Continue

Study Objective: To attempt to confirm that the normal response to increased coronary blood flow is endothelium-dependent epicardial artery dilation and that in atherosclerosis this important endothelial function is not lost.

Technical Approach: We plan to study adult male and female patients ages 18 to 75 years who present with chest pain, a stable clinical course and suitable coronary anatomy at diagnostic catheterization. Patients with smooth (n=10), irregular (n=10), and stenosed (n=10) left anterior descending or non-dominant circumflex arteries will be studied. Twelve hours prior to catheterization, long acting nitrates, calcium-channel blockers, beta-blockers an dipyridamole will be held. Following diagnostic venous and arterial catheterization, including coronary arteriography, a 5 French pacing wire is placed in the right ventricle and an 8 French Judkins catheter is positioned in the ostium of the left coronary artery. A 2.5 French intracoronary Doppler catheter is positioned in the proximal left anterior descending or non-dominant circumflex artery and an additional 5,000 units of Heparin is given intravenously. Baseline coronary blood flow velocity, hemodynamics and a biplane coronary angiogram will be performed using non-ionic contrast (Omnipaque).

Number of subjects enrolled to date: 10
Number of subjects enrolled for reporting period: 4

Progress: Study going well.

Detail Summary Sheet

Date: 24 Oct 90 Prot No.: 88-25		Status: Ongoing
Title: Endothelial Dysfunction of Coronary Resistance Vessels		
Start Date:		Est Comp Date:
Principal Investigator(s) George S. Rebecca, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic May 90 Review Results Continue

Study Objective: To determine whether endothelial dysfunction in the microvasculature of patients with cardiomyopathies might be a cause of microvascular vasospasm manifested as inadequate vasodilator reserve.

Technical Approach: Patients admitted to the hospital with the diagnosis of hypertrophic cardiomyopathy, dilated cardiomyopathy, left ventricular hypertrophy due to hypertension and patients who may have normal hearts at the time of diagnostic heart catheterization will be asked to participate in the study. Twenty-four hours prior to catheterization, nitrates, calcium-channel blockers, and beta-blockers will be withheld. Following diagnostic venous and arterial catheterization, including coronary arteriography, a 5 French pacing wire will be positioned in the right atrium and an 8 French Judkins catheter will be positioned in the ostium of the left coronary artery. A 2.5 French intracoronary Doppler catheter is positioned in the proximal left anterior descending coronary artery and an extra 5000 units of Heparin will be given intravenously. Baseline coronary blood flow will be measured and a baseline coronary angiogram will be performed using non-ionic contrast (Omnipaque). We will evaluate coronary blood flow changes to intracoronary administration of acetylcholine and adenosine to assess small vessel endothelial function.

Number of subjects enrolled to date: 0
Number of subjects enrolled during reporting period: 0

Progress: Have not started this project yet.

Detail Summary Sheet

Date: 9 Nov 90 Prot No.: 88-27		Status: Completed
Title: Comparison of Cholesterol Lowering Properties of Psyllum Hydrophilic Mucilloid and Cholestyramine		
Start Date: 19 May 88		Est Comp Date: May 89
Principal Investigator(s) Arnold A. Asp, MD, MAJ, MC Mark A. Smith, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine, Clinical Investigation		Associate Investigators:
Key Words: Cholesterol, Cholestyramine, Psyllum		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the cholesterol lowering efficacy of cholestyramine, PHC and PHC/cholestyramine combination, and to assess degree of compliance, cost effectiveness and adverse effects of each regimen.

Technical Approach:
a. Design - Double blinded controlled prospective study.
b. Manpower - This study will require 2-4 hours per week of one medical resident (Dr. Smith) and one staff endocrinologist (Dr. Asp). Appropriate support by Pharmacy and Pathology has been coordinated through MAJ Almquist and COL Goodhue.
c. Funding: $6500.00

Number of subjects enrolled to date: 11
Number of subjects enrolled during reporting period:

Progress: Data collection complete. Statistical analysis and preparation for potential publication in progress. Adverse reactions were occasional mild gastrointestinal side effects from medication. No serious reactions. No reactions resulting in withdrawal from study.

Detail Summary Sheet

Date: 11 May 90 Prot No.: 88-29 Status: Terminated

Title: Clinical Multicenter Evaluation of Nifedipine GITS in Reducing the Total Ischemic Burden and Suppressing the Circadian Ischemic Surge in Patients with Symptomatic Coronary Artery Disease

Start Date:	Est Comp Date:
Principal Investigator(s) George S. Rebecca, MD, COL, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic May 90 Review Results Terminate

Study Objective: To try to clarify some of the issues regarding mechanisms of action of a new delivery system nifedipine GITS (Gastrointestinal Therapeutic System) compared to other antianginal therapies.

Technical Approach:

Number of subjects enrolled to date: 0
Number of subjects enrolled during reporting period:

Progress: This project was never implemented. Drug is now on the market, study is terminated at investigator's request.

Detail Summary Sheet

Date: 20 Apr 90 Prot No.: 89-18		Status: Terminated
Title: Microbiologic, Histologic, and Quantitative Urease Studies of Gastric Biopsies from Patients with Campylobacter pylore Associated Non-Ulcer Dyspepsia		
Start Date: Apr 89		Est Comp Date:
Principal Investigator(s) David R. Haburchak, M.D., COL, MC		Facility: Eisenhower Army Medical Centers
Dept/Svc: Medicine/Gastroenterology; Pathology/Anatomical Svc; Clinical Investigation/Pharmacology & Microbiol-Immuno Svcs Key Words:		Associate Investigators: Tu H. Nguyen, M.D., LTC, MC Donald E. Sutherland, PhD, MAJ, MS David K. Turgeon, PhD, CPT, MS Samuel M. Willis, Jr, M.D., MAJ, MC Frank R. Benton, M.D., LTC, MC Jack A. Horner, B.S. SGT Kathy Morris
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Apr 90 Review Results Terminated

Study Objective: To quantitate urease activity in gastric biopsies as a marker for gastric colonization with Campylobacter pylori.

Technical Approach: A four quadrant, random gastric antral mucosal biopsy specimen was obtained from patients with Campylobacter pylori associated non-ulcer dyspepsia. Biopsy materials were inoculated on Campylobacter blood agar and Campylobacter selective agar for microbiologic studies. The microorganism was identified on the basis of biochemical reactions (urease, catalase and others). For histologic studies, biopsy materials were obtained at endoscopy and were placed in 10% buffered formalin. All specimens from an individual patient embedded in a single block. Four 3 μm paraffin sections were placed on each of 4 slides. Two slides were stained with hematoxylin and eosin and two with the Warrthin-Starry silver stain. For electron microscopic examination, biopsy materials was obtained at endoscopy and placed in buffered glutaraldehyde. The Sigma kit was used for quantitation of ammonia in Christensen's urea broth as a means of quantitating urease activity.

Number of subjects enrolled to date: 3
Number of subjects enrolled for reporting period: 0

Progress: Terminate.

Detail Summary Sheet

Date: 24 Oct 90 Prot No.: 89-27		Status: Ongoing
Title: The Evaluation of Direct Vasoactive Properties of Enalaprilat (Vasotec IV) in Normal, Minimally Diseased, and Significantly Stenosed Epicardial Coronary Arteries.		
Start Date:		Est Comp Date:
Principal Investigator(s) George S. Rebecca, MD, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/ Cardiology		Associate Investigators: James H. Wilkin, MD, COL, MC
Key Words:		Edward A. Matthews, DO, MAJ, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic May 90 Review Results Continue

Study Objective: To evaluate the direct coronary vasoactive effects of enalaprilat. Using quantitative coronary angiography in conjunction with coronary blood flow measurements, direct evaluation of this drug on epicardia. coronary arteries will be studied. The study will encompass normal coronary arteries, as well as minimally diseased, and significantly stenosed arteries. The hypothesis is that enalaprilat will cause direct coronary vasodilation.

Technical Approach: All coronary arteriograms will be performed using power injection and non-ionic contrast. Baseline measurements will be taken and 1.25 mg intravenous enalaprilat will be given, with repeat measurements and and angiograms done at 20 minutes, 40 minutes, and 60 minutes. With regard to the patient, the patient would have this as part of a routine catheterization. The additional time in the catheterization lab would be approximately 30 to 40 minutes. The dye load used will be a non-ionic dye, which is generally accepted as being less toxic to the patient, and the additional amount of dye that the patient will receive will be approximately 40 cc's. Concurrent treatment of cardiac medications will be discontinued 24 to 48 hours prior to the study.

Number of subjects enrolled to date:
Number of subjects enrolled during reporting period: 0

Progress: Awaiting decision on Jackson Foundation funding.

Detail Summary Sheet

Date: 24 Oct 90 Prot No.: 89-28		Status: Ongoing
Title: The Evaluation of Mevacor (Lovastatin) in Regression of Coronary Atherosclerosis in Patients with Early Coronary Artery Disease.		
Start Date:		Est Comp Date:
Principal Investigator(s) George S. Rebecca, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology		Associate Investigators: Edward A. Matthews, DO, MAJ, MC James H. Wilkin, MD, COL, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic May 90 Review Results Continue

Study Objective: To evaluate the effect of lowering serum cholesterol over a 12-month period on adverse coronary reactivity.

Technical Approach: Using quantitative coronary angiography in conjunction with coronary blood flow measurements direct evaluation of the patient's coronary artery reactivity will be sudied in response to acetylcholine at baseline. Patients will require followup over a 12 month period with strict control of their serum cholesterol with Mevacor and subsequent catheterization, coronary angioplasty and repeat acetylcholine study.

Number of subjects enrolled for reporting period: 0

Progress: Awaiting decision on Jackson Foundation funding.

Detail Summary Sheet

Date: 14 Jun 1990 Prot No.: 89-39		Status: Terminated
Title: Cytogenetics and Correlative Flow Cytometry in Multiple Myeloma and Waldenstrom's Macroglobulinemia Patients.		
Start Date: Aug 89		Est Comp Date: Aug 91
Principal Investigator(s) Christopher G. Acker, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Oncology-Hematology		Associate Investigators: David R. Bryson, MD, MAJ, MC K.L. Satya-Prakash, PhD John S. Krauss, MD
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To identify consistent chromosomal abnormalities in patients with Multiple Myeloma (MM) and Waldenstrom's Macroglobulinemia (WM), and to correlate cytogenetic findings with data from DNA/RNA/gene product flow cytometry (FCM) and conventional clinical evaluation.

Technical Approach:

Progress: Study never implemented, terminate at request of investigator.

Detail Summary Sheet

Date: 12 Sep 90 Prot No.: 89-40		Status: Ongoing
Title: Phase II Study of Anagrelide for Thrombocytosis Secondary to Myeloproliferative Disorders		
Start Date: May 90		Est Comp Date:
Principal Investigator(s) Mark R. Keaton, M.D., MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Compassionate treatment protocol.

Progress: Four patients have been enrolled on the Anagrelide protocol at Eisenhower Army Medical Center. Currently three are on therapy here with one patient's care transferred to Brooke Army Medical Center due to reassignment. All patients have had a good response to therapy with minimal to no toxicity. Since this is a compassionate treatment protocol because Anagrelide is effective, but not currently available, it is our plan to continue patients on therapy as long as it remains effective or toxicity intervenes.

Detail Summary Sheet

Date: 8 Nov 90 Prot No.: 89-48		Status: Terminated
Title: C-Reactive Protein Levels in the Diagnosis of Fungal Infections in HIV Positive Patients.		
Start Date:		Est Comp Date:
Principal Investigator(s) Christopher G. Acker, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Infectious Disease		Associate Investigators: David R. Haburchak, MD, COL, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To correlate quantitative CRP level with positive fungal blood cultures, as well as CRP level response to anti-fungal therapy in HIV positive patients.

Technical Approach: HIV Stage VI patients not currently receiving antimicrobial therapy, with temperatures greater than 100.5 degrees F., will be pan cultured in the usual fashion, to include fungalcultures by the DuPong Isolator System. Quantitative CRP levels will also be obtained at the time of culturing. In the event anti-fungal therapy is started, CRP levels will be followed at 24 hours, as well as 2, 4, 8 and 10 days after initiation of therapy.

Progress: Due to inability to obtain specimens correctly, this protocol was not continued.

Detail Summary Sheet

Date: 24 Oct 90 Prot No.: 90-2 Status: Terminated

Title: INH Therapy Effects on Vitamin D and Calcium Metabolism.

Start Date:		Est Comp Date:
Principal Investigator(s) Donald A. Dubois, MD, USPHS		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Pulmonary Disease		Associate Investigators: Arnold A. Asp, MAJ, MC Richard F. Kucera, MAJ, MC William Johnson, COL, MC James C. McPherson, PhD A Dingbaum, MAJ, AN William W. Goodhue, COL, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To study if INH therapy alters vitamin D and or calcium metabolism in a significant manner.

Technical Approach: An open observational study following the effects of INH therapy on Vitamin D and calcium.

Progress: The study is terminated without any subjects enrolling in the protocol. The principal investigator and an associate investigator have PCS'd.

Detail Summary Sheet

Date: 18 Sep 90 Prot No.: 90-5		Status: Ongoing
Title: Effect of Bile-Salt Binding Agents in Enterohepatic Circulation of Thyroxine.		
Start Date: Feb 90		Est Comp Date:
Principal Investigator(s) Mark Marino, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Internal Medicine		Associate Investigators: MAJ Arnold A. Asp, MD, MC CPT Robert M. Tuttle, MD, MC CPT Mark Smith, MD, MC CPT Jo T. Goolsby, MD, MC CPT Michael Rave, MC CPT John Wendt, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare thyroid hormone levels before and during short-term therapy with colestipol.

Technical Approach: Thyroid function tests will be drawn on alternating days during the two weeks that bile-salt binding agents will be administered. The subjects will be assessed on a daily basis.

Progress: Thyroxine is deiodinated in the liver and iodinated byproducts are excreted as glucuronide conjugates and sulfate esters through the biliary system. Enterohepatic circulation of these iodinated products contribute significantly to the total hormone pool in some species, however the importance of this pathway in man is uncertain. Cholestyramine, a basic anion exchange resin, significantly decreases the bioavailability of exogenous thyroxine and, because of bile salt malabsorption, may also interfere with enterohepatic reclamation of endogenous iodinated products. Since reduction in ambient serum T4 and T3 levels by as little as 15% may stimulate significant elevation in TSH (>50%), thyroid hormone and TSH levels were assessed prior to and during therapy with cholestyramine.

Four euthyroid male volunteers were evaluated with physical examinations, TSH, T4, T3, T3U, TSH were collected at 1000 hrs an alternating days over two weeks. Cholestyramine 4 grams was administered twice daily for 14 days and T4, T3, T3RU, TSH collected at 1000 hrs on alternating days over two weeks.

Samples were frozen at -20°C and processed simultaneously at the conclusion of therapy. Mean and standard deviation of each individual's pre- and post-therapy values were compared and 95% confidence intervals established. No statistical differences were noted in these values.

90-5, Continued

	T4(ug/dl)				T3(ng/dl)			
Subject:	I	II	III	IV	I	II	III	IV
∓Pre-Rx:	7.30	6.50	5.52	8.88	161	146	184	192
∓Post-Rx:	7.66	7.18	5.99	9.31	177	164	188	202

	TSH (uU/ml)				T3RU (%)			
Subject:	I	II	III	IV	I	II	III	IV
∓Pre-Rx:	1.93	2.42	2.23	1.57	35.1	32.6	33.7	31.5
∓Post-Rx:	2.06	2.29	2.47	1.89	35.2	33.3	33.1	30.5

Interference with enterohepatic circulation would be expected to reduce T4 and T3 levels and stimulate TSH synthesis. This prospective study reveals no significant change in these values and suggests little effect on thyroid hormone disposition by ile-acid binding agents in standard doses.

Detail Summary Sheet

Date: 23 Mar 90 Prot No.: 90-7 Status: Terminated

Title: Fludarabine for Treatment of Waldenstrom's Macroglogulinemia.

Start Date: Nov 89		Est Comp Date:
Principal Investigator(s) David R. Bryson, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Hematolgoy-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Emergency use drug.

Technical Approach:

Progress: On 1 Dec 89 the drug was stopped because the patient did not respond.

Detail Summary Sheet

Date: 7 Nov 90 Prot No.: 90-11 Status: Ongoing

Title: Pentostatin for Treatment of Waldenstrom's Macroglobulinemia.

Start Date: Feb 90		Est Comp Date:
Principal Investigator(s) David R. Bryson, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Emergency use drug for one patient.

Progress: Patient had good response as measured by bone marrow biopsy and improved blood count. Patient is still on medication.

Detail Summary Sheet

Date: 24 Oct 90 Prot No.: 90-12 Status: Ongoing

Title: Coronary Reactivity in Response to Nitrous Oxide Inhalation.

Start Date:		Est Comp Date:
Principal Investigator(s) George S. Rebecca, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology		Associate Investigators: Michael Goldfinger, MD, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To study patients with various degrees of coronary artery disease or normal coronary arteries to evaluate the coronary diameter and flow character in response to nitrous oxide.

Technical Approach:

Progress: Study not yet started.

Detail Summary Sheet

Date: 18 Oct 90 Prot No.: 90-16 Status: Ongoing

Title: Study of Vespa Fire Ant Venom in the Diagnosis of Fire Ant Reactivity.

Start Date:	Est Comp Date:
Principal Investigator(s) Chitra Kuthiala, MD, COL, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Allergy	Associate Investigators: Chester Stafford, M.D.
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare skin test reactivity of Vespa fire ant venom to that of two commercially available IFA whole body extract preparations.

Technical Approach:

Number of subjects enrolled to date: 12
- Patients with systemic reactions to fire ant stings 7
-Non-allergic control subjects 5

Progress: No adverse reactions occurred except for delayed local reactions to higher concentrations of whole body extract (WBE). All patients had positive skin tests to both whole body extract and fire ant venom; however, a significant number of controls had false positive skin tets to WBE, suggesting that fire ant venom may be more specific in the diagnosis of fire ant allergy.

Detail Summary Sheet

Date: 11 Oct 90 Prot No.: 90-24		Status: Ongoing
Title: Metabolic Factors Influencing Myocardial Recovery from Acidosis.		
Start Date:		Est Comp Date:
Principal Investigator(s) Richard F. Kucera, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Pulmonary-Critical Care		Associate Investigators: Joseph I. Shapior, MD
Key Words:		Laurence Chan, MD, PhD Univ of Colorado
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the metabolic mechanisms by which cardiac function is depressed during severe acidosis and the pharmacologic maneuvers by which functional recovery may be enhanced or accelerated.

Technical Approach:

Progress: Awaiting USMRDC grant decision.

Detail Summary Sheet

Date: 24 Oct 90 Prot No.: 90-27 Status: Ongoing

Title: Diurnal Changes in Coronary Artery Vasodilating Properties.

Start Date:		Est Comp Date:
Principal Investigator(s) George S. Rebecca, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology		Associate Investigators: Anthony Chappell, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the coronary diameter and flow characteristics in response to stress of a mental arithmetic problem and infusions of adenosine and acetylcholine.

Technical Approach:

Number of subjects enrolled for the reporting period: 0

Progress: Study not yet started.

Detail Summary Sheet

Date: 11 Sep 90 Prot No.: 90-31		Status: Ongoing
Title: Treatment of HIV Associated Anemia with Recombinant Human Erythropoietin (EPREX)		
Start Date:		Est Comp Date:
Principal Investigator(s) Jeffrey L. Lennox, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Infectious Disease		Associate Investigators: Daniel B. Craig, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective:

Technical Approach:

Number of subjects enrolled to date:

Progress: HSC approval recently received, no reportable data.

Detail Summary Sheet

Date: 20 Sep 90 Prot No.: 90-33		Status: Ongoing
Title: National Cancer Institute (NCI) Protocol I89-18 Fludarabine Phosphate in Patients with Refractory Chronic Lymphocytic Leukemia		
Start Date:		Est Comp Date:
Principal Investigator(s) Mark R. Keaton, MAJ, MD, MC		Facility: Eisenhower Army Medial Center
Dept/Svc: Medicine/Oncology-Hematology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Emergency treatment use.

Progress: Local approval Sep 90, no reportable data.

Detail Summary Sheet

Date: 24 Oct 90 Prot No.: 89-15		Status: Completed
Title: An Evaluation of the Effect on Self-Esteem by Weight Loss and Participation in Peer Support Group in Patients with Vertical Banded Gastroplasty		
Start Date: Apr 89		Est Comp Date: Sep 90
Principal Investigator(s) Richard D. Boggan, MAJ, AN		Facility: Eisenhower Army Medical Center
Dept/Svc: Nursing		Associate Investigators:
Key Words: Obesity, Social support, Self-esteem,		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 90 Review Results Continue

Study Objective: To evaluate the self-esteem of the morbidly obese patient either prior to or immediately after surgery and contrast the results by having the patient take the same instrument 12 months after being involved in a structured, comprehensive maintenance program with a support group for this period of time. It is hypothesized that as one experiences weight reduction toward one's ideal baody weight, self-esteem will greatly improve with the assistance of a support group.

Technical Approach: Established two groups of subjects as part of the study: 1) primary experimental group who were able to attend group sessions and be actively involved in the study. This group would be involved in a comprehensive management program utilizing the LEARN approach. 2) Control group who are unable to participate in the group sessions, but who are willing to take the questionnaire by mail and again in twelve months along with a follow up questionnaire. The Multidimensional Self-Esteem Inventory (MSEI) would be used as the assessment tool.

Progress: The study started with a great deal of enthusiasm with the subjects from 25 May 89 until the last of September 1990. From these sessions it became quite evident that the majority of the subjects were depending upon surgical intervention totally for the weight loss, resistent to modify behavior patterns but attended group sessions for the social interaction. Weight loss was minimal and in many cases subjects regained loss. Number of subjects was greatly reduced to only six. During the study many weaknesses in the research design were observed and was a very effective learning exercise on the research process for a beginning researcher. A stronger awareness of the needs of these patients was developed among the nursing staff and physicians in which an increase in support is now being provided. The study was terminated due to a question regarding the validity of the data based upon the design. Therefore, final data collection was not accomplished. A new patient education program is under development by nurses on the surgical wards using the literature studies obtained from this study.

89-15 Continued

There were 18 subjects in the original experimental group with only 6 subjects remaining when the study was terminated. Out of 18 subjects in the control group, only 2 remained in contact with the investigator.

Since no drugs were used, there were no adverse drug reactions to report.

Result of the study provided positive reinforcement on patient needs and a focus upon the personal needs of these patients. There were no negative outcomes of the study that affected any patient, staff, or the institution.

Number of subjects enrolled to date: 36
Number of subjectes enrolled for the reporting period: 10

Detail Summary Sheet

Date: 7 Nov 90 Prot No.: 90-29		Status: Ongoing
Title: Variation of Content Exposure in the Dwight David Eisenhower Army Medical Center Preceptorship Program and Junior Nurse Corp Officer Attitudes of Retention		
Start Date: Jul 90		Est Comp Date:
Principal Investigator(s) Crystal Chatman, 1LT, AN		Facility: Eisenhower Army Medical Center
Dept/Svc: Nursing		Associate Investigators: Patricia Clay, MAJ, AN
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective:

Technical Approach:

Progress: Questionnaires completed, analysis ongoing.

Detail Summary Sheet

Date: 6 Nov 90 Prot No.: 89-29		Status: Ongoing
Title: Use of the Vira pap to Plan Therapy for HPV Associated Lesions of the Cervix.		
Start Date:		Est Comp Date:
Principal Investigator(s) John W. Spurlock, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Obstetrics-Gynecology, Clinical Investigation, Pathology		Associate Investigators: Terrel Michel, MD, COL, MC Gary B. Broadnax, DO, COL, MC Tu H. Nguyen, MD, LTC, MC David K. Turgeon, PhD, CPT, MS
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic May 90 Review Results Continue

Study Objective: To determine the prevalence of HPV in our active duty female population. To identify the strain of HPV in patients with an abnormal Pap smear.

Technical Approach: Population will be a random sample of routine GYN patients coming in for a Pap smear. A Pap smear and Vira pap will be done on these patients. If both tests are negative they will receive routine followup. If the Pap smear and/or the Vira pap is positive they will have a colposcopy done. If the colposcopy records only warty changes and the strain is 6 or 11, they will be randomized into a treat vs non-treatment group. The treatment group will have laser vaporization of the cervix. The non-treatment group will be followed with Pap smear/colposcopy every 3-4 months. If the colposcopy or the strain of virus is of a high risk group (16, 18, 31) they will all be treated with laser ablation.

Progress: Project has not been started.

Detail Summary Sheet

Date: 25 Apr 90 Prot No.: 85-30		Status: Terminated
Title: Family Risk and Protective Factors: A Prospective Study of Obstetric Patients and Their Families.		
Start Date: Aug 85		Est Comp Date:
Principal Investigator(s) Frederick Garland, PhD, MAJ, MC Peter S. Jensen, M.D., MAJ, MC		Facility: USAMEDDAC, Ft Jackson, SC Eisenhower Army Medical Center
Dept/Svc: Psychiatry-Neurology/Social Work Service		Associate Investigators: Kent M. Plowman, MD, LTC, MC Stephan N. Xenakis, MD, COL,MC Donald W. Grogan, MD, MAJ, M
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Apr 90 Review Results Terminate

Study Objective: This study will determine the additive effects of stress, lack of social supports, parental history, parental coping skills, and marital communication on complications of pregnancy in the mother and newborn, and effects of these factors on the child's growth and development.

Technical Approach: One hundred and forty nulliparous women in the first or second trimester of pregnancy and their husbands will be invited to participate in the study. Subjects and spouses will complete surveys to determine their level of social supports, stress, coping skills, marital relationships, etc. These families will be followed prospectively through the course of pregnancy, into the child's first year of life. Statistical analyses will be performed to assess the relationship between interior (stress, supports, coping, etc.) variables and outcome measures (complications of pregnancy, child's growth and development, frequency of illness, etc.).

Number of subjects enrolled to date: 120
Number of subjects enrolled for reporting period: 20

Progress: Funding not approved, terminate at investigator's request.

Detail Summary Sheet

Date: 25 Jan 90 Prot No.: 87-10		Status: Completed
Title: Neuropsychiatric and Psychosocial Aspects of HIV Disease.		
Start Date: Oct 87		Est Comp Date:
Principal Investigator(s) Louis Duchin, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry & Neurology		Associate Investigators: Stephen Xenakis, MD, COL, MC Peter S. Jensen, MD, MAJ, MC Fred Tamayo, MAJ, MS
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate neuropsychiatric/psychosocial/unit functioning of HIV positive soldiers.

Technical Approach: Self report, rater report, neuropsychiatric quesitonnaires/evaluations. No funding or personnel assigned as yet.

Number of subjects enrolled to date: 78
Number of subjects enrolled for reporting period: 3

Progress: This study examined the effects of human immunodeficiency virus seropositivity on mood and mentation in asymptomatic individuals. Fifty-three HIV-seropositive soldiers and 25 HIV-seronegative controls matched for age, sex, and level of education underwent a standardized neuropsychological test battery, and completed a psychosocial assessment questionnaire, as well as self-report instruments of mood. A neuropsychological impairment index, based on nine measures of cognitive functions, was prepared. The HIV-seropositive soldiers showed decreased coping skills, higher anxiety, and a relative increase in depression . There were significant differences in six of the ten scales of the MMPI across groups: the Schizophrenia Scale was clinically elevated within the HIV-seropositive group. The HIV-seropositive soldiers performed in the borderline impaired range on the Stroop Test, and exhibited poorer visual memory than controls. The Impairment Index was significantly higher in the HIV-seropositive group and fell within the borderline-impaired range. There was no correlation between neuropsychological/mood variables and time since seroconversion, stage, or CD4 count. Neuropsychological score differences could not be accounted for by measures of depression or anxiety, suggesting that these differences reflect an organically-based compromise of neurobehavioral functioning.

Detail Summary Sheet

Date: 17 Oct 90 Prot No.: 87-45 Status: Ongoing

Title: Child Psychiatric Data Base Project

Start Date: Jul 87	Est Comp Date:
Principal Investigator(s) Peter S. Jensen, MD, MAJ, MC Alan M. Josephson, MD Perry L. Wolf, MAJ, MS	Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry & Neurology, Social Work Svc	Associate Investigators: Don O'Brien, LTC, MS Ms Marilyn Reedy Earl Loomis, MD, MCG Alex Mabe, PhD, MCG Robert C. Ness, PhD, MCG Harry Davis, M.S., MCG R. Adair Blackwood, MD, Charter Hosp Joseph Frey, PhD, MCG
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To facilitate the development of a collaborative data base and computer scoring system of data items completed by parents or the child's main caretaking figures.

Technical Approach: The 94-item data instrument is presently in use in our routine child psychiatric evaluative settings.

Number of subjects enrolled to date: 600
Number of subjects enrolled for reporting period: 600

Progress: Approximately 600 subjects have been enrolled to date. The hospital has purchased an NCS 7004 Scanner which facilitates the scanning of questionnaires. Medical Centers at Tripler and Walter Reed have also implemented this protocol, and are sending their data base questionnaires to us for scanning.

Detail Summary Sheet

Date: 10 Oct 90 Prot No.: 89-9		Status: Ongoing
Title: The Relationship Between Conflict and Social Development in Latency Aged Children.		
Start Date:		Est Comp Date:
Principal Investigator(s) Frederick N. Garland, PhD, MAJ, MS		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry/Psychology		Associate Investigators: Perry Wolfe, DSW, MAJ, MS
Key Words:		Ms Wendy A. O'Day, BA
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare accuracy in identifying affective facial cues between physically abused and non-abused children. To compare perceptual, cognitive and affective perspective-taking skills between physically abused and non-abused children while controlling for differences in intelligence and age. To determine the influence of perspective-taking skills on p nt perceptions of behavioral problems in the home.

Technical Approach: A 2x2 (abuse/nonabuse x age) factorial design. No manpower demand on hospital staff.

No adverse reactions.

Number of sujects enrolled to date: 70
Number of subjects enrolled during reporting period: 5

Progress: Data collection completed and analyses will begin as soon as P&N's SPSS program is operational. Anticipate submission (unless results differ from preliminary results of last year) for publication in winter.

Detail Summary Sheet

Date: 27 Sep 90 Prot No.: 89-11		Status: Ongoing
Title: Correlation Between Treatment Response and Ventricular Size in Patients Experiencing Their First Psychotic Break.		
Start Date: Mar 89		Est Comp Date: Sep 91
Principal Investigator(s) Linton S. Holsenbeck, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry		Associate Investigators: Robin Hostetter, MD, LTC, MC
Key Words:		Dr. Richard Borison
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: This study will examine response to treatment in a prospective fashion using a widely available instrument (BPRS). The study participants have a high likelihood of remaining available for longitudinal followup through the Army medical system.

Technical Approach:

Number of subjects enrolled to date: 34
Number of subjects enrolled during reporting period: 18

Progress: The project is continuing with LTC Hostetter the current director during COL Holsenbeck's absence.

Detail Summary Sheet

Date: 24 Apr 90 Prot No.: 89-31		Status: Terminated
Title: The Impact of Self versus Spouse Visual Perspective on Attributions in Distressed Marital Couples.		
Start Date: Jun 89		Est Comp Date: Dec 89
Principal Investigator(s) Daniel W. Clark, CPT, MS		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry & Neurology/Psychology		Associate Investigators:
Key Words: Attribution, Marital conflict		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare attributions of blame in the view self condition versus the view spouse condition across the three sampling periods of pre-interaction, post-interaction and post-replay.

Technical Approach:

Number of subjects enrolled during reporting period: 0

Progress: Terminated administratively, investigator PCS'd without submitting a report.

Detail Summary Sheet

Date: 10 Oct 90 Prot No.: 89-33		Status: Completed
Title: Repetition of the Interpersonal Behavior Patterns of Physically Aggressive Families of Origin in Young Adults' Dating Behavior Patterns.		
Start Date: Jun 89		Est Comp Date: Dec 89
Principal Investigator(s) Darlene S. Polek, B.A.		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry & Neurology/Psychology		Associate Investigators: Frederick N. Garland, PhD, MAJ, MS
Key Words: Aggressive, Family, Dating		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To identify the interactive behaviors that are related to the use of physically aggressive conflict resolution tactics in families and in dating relationships. To determine the process by which children learn aggressive behavior from their parents and imitate that in their own adult intimate relationships.

Technical Approach: Retrospective reports of families and dating relationships of 392 unmarried male and female students and military personnel between the ages of 18 and 25 were collected by means of anonymous questionnaires. A multivariate regression model was utilized to analyze the data.

Progress: The results demonstrated intergenerational repetition of physical aggression (both perpetrator and victim roles), social isolation, and cohesion pathology. Cohesion style, decision-making pathology, and fathers' control styles were repeated by males only. Intergenerational repetition of physical aggression, predictions of future involvement in marital aggression, and attitudes supportive of marital aggression were more common for males than females. Factors that facilitated, disinhibited, and inhibited repetition of aggression were identified. Evidence for a pathological family system of interactive behaviors was found when fathers had been aggressive toward subjects as children. While aggressive dating relationships were characterized by some pathological behavior patterns, there was little evidence to support a systemic interpretation. A comparison was made between social learning theory and family systems theory, with the conclusion that an integration of the two best explained the results.

Detail Summary Sheet

Date: 17 Oct 90 Prot No.: 90-8		Status: Terminated
Title: The Treatment of Preschool Children (4-6 years of age) Using Group Play Therapy and Parental Education.		
Start Date: Feb 90		Est Comp Date:
Principal Investigator(s) William S. Evans, Jr., MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Child Psychiatry & Neurology		Associate Investigators: Frederick Garland, PhD, MAJ, MS Joseph Whitfield, MD, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Objective: To study the clinical efficiency of group play therapy on a pre-school population of behaviorally or socially disordered children.

Technical Approach:

Progress: Study didn't get started, PI has been deployed, terminate per AI's instructions.

Detail Summary Sheet

Date: 24 Oct 90 Prot No.: 90-23		Status: Ongoing
Title: Investigation of Organic Correlations with Elevated ADH in Schizopheniform Disorder		
Start Date:		Est Comp Date:
Principal Investigator(s) Joseph A. Whitfield, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To attempt to determine if there is a structural marker taht would predict the increase of ADH, and give us a better understanding of the etiology and physiology of psychosis.

Technical Approach: First break psychotic patient will have an ADH level drawn along with a CT, an EEG, and rating of psychosis done on admission. A statistical comparison will be made between elevateed ADH levels and abnormalities on CT, EEG, and psychotic rating scales.

Number of subjects enrolled for the reporting period: 6

Progress: Six subjects enrolled, no analysis has been done so far.

Detail Summary Sheet

Date: 20 Sep 90 Prot No.: 90-34		Status: Ongoing
Title: The Demographics of Patients with Late Luteal Phase Dysphoric Disorder as Seen in a Military Care Setting		
Start Date: Sep 90		Est Comp Date:
Principal Investigator(s) Joseph A. Whitfield, CPT, MD, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry & Neurology		Associate Investigators: David Schenk, CPT, MD, MC James Reed, MAJ, MD, MC James Williford, CPT, MD, MC Charles Perrotta, CPT, MD, MC William Evans, MAJ, MD, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the demographics of a population with late luteal phase dysphoric disorder as seen in a military setting. The implications of this data on care in the military system will be explored.

Technical Approach: The study involves several questionnaires and venipuncture in conjunction with a physical examination.

Progress: Local approval in September, no reportable data.

Detail Summary Sheet

Date: 20 Sep 90 Prot No.: 90-35		Status: Ongoing
Title: Social Supports of Service Members with HIV Spectrum Disease		
Start Date: Sep 90		Est Comp Date:
Principal Investigator(s) Azra Pappa, CPT, DO, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry & Neurology		Associate Investigators: William Evans, MAJ, MD, MC Christopher Welch, LTC, MD, MC Donald Edwards, PA
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To look at active duty service members, their adjustment and functioning based on actual and perceived social supports.

Technical Approach: The data will be gathered over six months with planned enrollment from 8-10 patients a week with an overall patient number of 100 as the expected total. Three categories of subjects will be identified: 1) newly diagnosed HIV+, 2) restaging, and 3) TDRL evaluations. Each subject will be administered the UCLA social support questionnaire along with a brief demographic questionnaire.

Progress: Local approval in Sep, no reportable data.

Detail Summary Sheet

Date: 11 Sep 90 Prot No.: 90-1		Status: Ongoing
Title: Technetium 99m Antimony Trisulfide Colloid for Investigation of Lymphatic Drainage.		
Start Date:		Est Comp Date:
Principal Investigator(s) Stephen G. Oswald, MD, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Radiology/Nuclear Medicine		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To provide a radiopharmaceutical whereby lymphatic drainage may be characterized.

Technical Approach:P Intradermal injection of radiolabeled colloidal particles with serial gamma camera images to evaluate lymphatic drainage.

Number of subjects enrolled to date: 0.

Progress: No requests for lymphoscintigraphy during this period. Study is considered ongoing.

Detail Summary Sheet

Date: 11 Sep 90 Prot No.: 90-22		Status: Ongoing
Title: In vitro Labeling of Red Blood Cells with Technetium 99 Utilizing a Pre-prepared "Kit."		
Start Date:		Est Comp Date:
Principal Investigator(s) Stephen G. Oswald, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Radiology/Nuclear Medicine		Associate Investigators: Robert J. Kaminski, LTC, MC James H. Corley, LTC, MC Melissa McMillan, MAJ, MC Robert Scharstein, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To provide a mechanism whereby this agent is available for use in diagnostic sudies where a reliable and consistent method of achieving optimal labeling of red blood cells is needed.

Technical Approach:

Progress: Have just received HSC approval to proceed. No patients entered as yet.

Detail Summary Sheet

Date: 18 Sep 90 Prot No.: 90-36		Status: Ongoing
Title: Treatment of Internal Contamination by Plutonium and Other Transuranic Elements with Two Investigational New Drugs (Ca-DTPA and Zn-DTPA)		
Start Date:		Est Comp Date:
Principal Investigator(s) Robert J. Kaminski, LTC, MD, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Radiology/Nuclear Medicine		Associate Investigators: Stephen G. Oswald, MD, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Objective: The principal objective of this protocol is to obtain approval from the IRC to use Ca-DTPA and Znn-DTPA for the treatment of patients at Eisenhower Army Medical Center who are internally contaminated with plutonium or other transuranic elements.

This is not an investigational study, approval allows us to store the drugs at this facility.

Detail Summary Sheet

Date: 10 Oct 90 Prot No.: 84-1		Status: Ongoing
Title: The DDEAMC Alcohol Residential Treatment Facility Patient Outcome Study.		
Start Date: Oct 83		Est Comp Date:
Principal Investigator(s) Daniel Hendricks, M.D.		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry and Neurology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To better understand alcoholism and its treatment by assessing some of its biological, psychological, and social concomitants, and determining their diagnostic and prognostic validity.

Technical Approach:

1. Summary of Experimental Design: This study is prospective in design. Measures of the above mentioned variables will be taken prior to, and upon completion of, treatment. Additionally, follow-up questionnaires are to be completed by the patient, spouse, and patient's commander at intervals of twelve months after discharge. Relationships will be measured using analysis of variance and analysis of covariance procedures.

2. Manpower: Personnel required to gather, collate, and interpret the data are, at a minimum, one 91G Behavioral Science Specialist, one Medical Records Technician, and one Clinical Psychologist.

3. Funding: Not applicable.

4. Number of subjects enrolled to date: 140

5. Number of subjects enrolled during reporting period: 0

6. Adverse reactions: None.

Progress: Data analysis continues, two papers in preparation.

Detail Summary Sheet

Date: 11 Sep 90 Prot No.: 90-13 Status: Ongoing

Title: Long Term Evaluation of the Effect of Desipramine on Cocaine Use.

Start Date:	Est Comp Date:
Principal Investigator(s) Carolyn D. Randle, MD, LTC, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Residential Treatment Facility	Associate Investigators: Daniel Hendricks, M.D.
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the long term effect of Desipramine on cocaine dependent patients, and to evaluate the short term effects of Desipramine on craving by cocaine dependent patients while on inpatient status as well monitor adverse reactions in a controlled situation

Technical Approach:

Progress: Study not yet implemented, awaiting DA approval.

Detail Summary Sheet

Date: 23 Oct 90 Prot No.: 78-14		Status: Ongoing
Title: Intraocular Lens Study.		
Start Date: May 78		Est Comp Date:
Principal Investigator(s) Kenneth Y. Gleitsmann, MD		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words: Intraocular Lens Implant Ophthalmology Aphakia Surgery		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Nov 89 Review Results Continue

Study Objective: Implantation of intraocular lenses in accordance with previously established FDA protocol.

Technical Approach:

Number of subjects enrolled to date: 888
Number of subjects enrolled for reporting period: 0

Detail Summary Sheet

Date: 18 Sep 90 Prot No.: 83-24		Status: Ongoing
Title: Assessment of Vertical Banded Gastroplasty in Treatment of Morbid Obesity.		
Start Date: Apr 83		Est Comp Date:
Principal Investigator(s) Ross S. Davies, M.D., COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery Medicine Psychiatry and Neurology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if vertical banded stapling is an effective treatment modality for morbid obesity, to determine its long term effectiveness and complications, and to determine if it will prevent the detrimental effects of morbid obesity.

Technical Approach: Weight loss post bypass will be studied in each patient and compared to average weight loss from other centers following the same procedure. Psychologic testing post-operative will be compared to pre-operative results to examine patient self-image pre and post weight loss.

Subjects enrolled to date: 250
Subjects enrolled for reporting period: 50

Progress: All reoperations have been studied and presented at a national meeting. Study continues per assigned protocol.

Detail Summary Sheet

Date: 10 Sep 90 Prot No.: 83-27		Status: Ongoing
Title: Microsurgery Skill Lab.		
Start Date: Nov 83		Est Comp Date:
Principal Investigator(s) Roberto H. Barja, MD COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic		Associate Investigators: MAJ Edward Hemphill, MD, MAJ, MC Stephen Simpson, MD, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 90 Review Results Continue

Study Objective: In depth exposure to the principles and techniques of microsurgery in a laboratory setting - skills developed being transferable to clinical setting - may also stimulate interest in further research related to field of microsurgery.

Technical Approach: Monthly orthopedic rotation in microvascular surgery for residents with special emphasis on microvascular repair of rat femoral arteries. Surgical application: suture of very small vessels and nerves. The project is being done in periods of 30 to 60 days by one resident and one staff.

Progress: Twelve microsurgery sessions conducted with two residents trained.

Detail Summary Sheet

Date: 10 Sep 90 Prot No.: 84-25		Status: Terminated
Title: Comparison of Thermography and Standard Techniques for Detection, Diagnosis and Tracing of Peripheral Vascular Disease and Disorders Marked by Altered Patterns of Peripheral Blood Flow.		
Start Date: Mar 84		Est Comp Date:
Principal Investigator(s) Roberto H. Barja, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedics Clinical Investigation		Associate Investigators: Robert Anderson, MD, LTC, MC Larry Walker, MD, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the optimal utilization of thermography in clinical evaluation of the vascular status of the affected area. This phase of the project is concentrating on correlating near surface blood flow patterns with reports of pain having varied diagnostic etiologies. The aim is to determine whether thermography is a more sensitive and objective method for initially diagnostic and subsequently tracking pain problems with vascular components than current methods.

Technical Approach: Subjects are recorded thermographically as soon as a patient meeting the eligibility criteria requests treatment. This forms a part of the regular work-up for diagnosis of pain in the Orthopedic Clinic. A series of recordings are made as the patient progresses through treatment and follow-up. The results are then compared with the results of the standard clinical evaluation.

Number of subjects enrolled to date: 329
Number of subjects enrolled for reporting period: 0

Progress: Study terminated due to lack of technicial support.

Detail Summary Sheet

Date: 10 Sep 90 Prot No.: 85-5		Status: Ongoing
Title: Advanced Trauma Life Support Course.		
Start Date: Jan 85		Est Comp Date:
Principal Investigator(s) Stephen M. Gooden, MD, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 90 Review Results Continue

Study Objective: To provide training for physicians who are not dealing with major trauma on a day-to-day basis, and who may have to evaluate the seriously injured patient during the period immediately after injury. Also, it is intended to provide the basic knowledge and skills necessary to identify those patients whose need is for rapid assessment, resuscitation, and stabilization.

Technical Approach:

a. Design: The Advanced Trauma Life Support Course is a two day training session in which participants are given didactic instruction followed by practical skill stations and an animal lab. Testing is accomplished by a written exam and a practical exercise in which a simulated trauma victim is resuscitated.

b. Manpower: Requirements are as follows:

Course Director (1 MC)
Course Administrator (MS)
Instructors (6 MC)
Logistical Support (2 EM)
Moulage patients (4 EM)

c. Funding: Administrative cost derived from Office of Medical Education.

Progress: We have not conducted an ATLS Course in FY 90 because of manpower problems. We anticipate a course in early 1991.

Detail Summary Sheet

Date: 24 Aug 90 Prot No.: 87-9 Status: Terminated
Title: Iontophoresis of Steroids: Does it Affect Rabbit Tendon Strength.

Start Date: May 87		Est Comp Date:
Principal Investigator(s) Paul J. Herzwurm, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 90 Review Results Terminate

Study Objective: To study the effect of iontophoresis of steroids on rabbit tendon strength.

Technical Approach: The study was performed last May but we ran into technical difficulties in clamping the tendons when testing their tensile strength.

Progress: Unable to resolve technical problems, terminate at investigator's request.

Detail Summary Sheet

Date: 10 Sep 90 Prot No.: 88-5		Status: Ongoing
Title: Investigation of Cryotreatment on the Epiphysis of Growing Rabbit Bones.		
Start Date:		Est Comp Date:
Principal Investigator(s) Roberto H. Barja, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 90 Review Results Continue

Study Objective: 1) To evaluate cryotherapy times on the epiphysis of 6 week old rabbits (right femur); 2) to examine both grossly and microscopically, the effects of cryotherapy on bone growth epiphyseal closure.

Technical Approach: A cryoprobe after surgical cut-down is applied to epiphyses in the distal right femur of 6 week old rabbits. Four weeks post-cryotreatment the rabbits are euthanized, then a surgical cut-down is performed to remove the right and left femur. The pathologist then determines the gross effect on growth plates and any deformities present on the right vs the left femur. Microscopic specimens of the cryotreated epiphyses are examined to evaluate remaining potential for growth, microvascular structures, and uniformity of cryological effects.

Progress: Three laboratory sessions conducted in FY 90. Two residents trained.

Detail Summary Sheet

Date: 17 Oct 90 Prot No.: 88-6		Status: Ongoing
Title: Distal Thigh Pain and Stress Tranfer in Uncemented Total Hip Arthroplasties. A Scintigraphic Analysis.		
Start Date:		Est Comp Date:
Principal Investigator(s) Stephen L. Simpson, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic		Associate Investigators: Frank R. Ebert, MD, MAJ, MC James H. Algeo, Jr., MD, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if anterior thigh pain in uncemented total hip arthroplasties is caused by distal stress transfer through the femor prosthesis.

Technical Approach: Routine bone scans will be done at various time intervals following cemented and uncemented total hip arthroplasties. The bone scan is an accepted method of evaluating hip prostheses, having demonstrated both prospectively and retrospectively excellent sensitivity and good specificity in detecting and defining abnormalities such as loosening, fracture, and infection.

Number of subjects enrolled to date: 53
Number of subjects enrolled for reporting period: 23

Progress: PI is on civilian rotation, unable to obtain report.

Detail Summary Sheet

Date: 17 Oct 90	Prot No.: 88-34	Status: Ongoing

Title: Stress Radiography in the Detection of Shoulder Instability

Start Date:		Est Comp Date:
Principal Investigator(s) Stephen L. Simpson, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic Service		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Stress radiography is an attempt to demonstrate abnormal motion of the glenohumeral joint, which may be done in the office setting and does not require the administration of an anesthetic. The purpose of this study is to perform a modified technique of stress radiography in several subgroups: 1) healthy volunteers without history of shoulder problems, 2) patients with generalized ligamentous laxity and shoulder pain, and 3) patients with traumatic glenohumeral subluxation and/or dislocation.

Technical Approach:

Progress: PI on civilian rotation, unable to obtain report.

Detail Summary Sheet

Date: 10 Sep 90 Prot No.: 89-16		Status: Terminated
Title: Evaluation of the Monticelli-Spinelli External Fixator in the Treatment of Severe Extremity Wounds		
Start Date: Apr 89		Est Comp Date:
Principal Investigator(s) Kenneth A. Pettine, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic		Associate Investigators: Ralph Morales, MD, CPT, MC Michael Janssen, MD Monroe Levine, MD Medical College of Georgia
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To study the efficacy of the Monticelli-Spinelli external fixator for the treatment of severe open comminuted fractures of the extremities.

Technical Approach:

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0

Progress: Terminate, investigator left service.

Detail Summary Sheet

Date: 3 Jan 90 Prot No.: 89-30		Status: Completed
Title: Retrograde Amnesia: A Comparison Study of Induction Doses of Midazolam and Thiopental.		
Start Date: Jun 89		Est Comp Date: Nov 89
Principal Investigator(s) Linda George, MAJ, AN		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Anesthesiology		Associate Investigators: Charles M. Morley, CPT, AN Laurie J. Sommers, CPT/ AN James Willis, CPT, AN
Key Words: Retrograde amnesia; Anterograde amnesia; Recall; Recognition; Midazolam; Thipoental		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To ascertain if retrograde amnesia is produced by an induction dose of intravenous midazolam when compared with an induction dose of intravenous sodium thiopental.

Technical Approach: Experimental design with one control group and one treatment group; each group will be further divided into three subgroups each, relating to the time that the testing tool is used (1, 3, or 5 minutes). Induction agents to be compared are sodium thiopental and midazolam hydrochloride.

Number of subjects enrolled to date: 58
Number of subjects enrolled during reporting period: 23

Progress: The results of this study reflect an absence of retrograde amnesia using intravenous midazolam (0.3 mg/kg) for induction in 26, ASA I and II patients. This study despite its limitations, could be replicated easily. One suggestion for a future study would include a larger subject population to determine if a rare occurrence of retrograde amnesia is present (the potential correlation between alcohol consumption and recall/recognition impairment could be documented as well). Another suggestion would be to test a patient's recall/recognition of unfamiliar and/or unemphasized stimuli pre-induction. Perhaps if less time is permitted to record and store an event, retrograde amnesia may be apparent. The use of midazolam as an induction agent has gained favorable acceptance; a thorough understanding of its impact on memory would warrant continued research of its pharmacologic properties.
Preliminary conclusion: It appears that subjects in the subgroup receiving Midazolam one minute after viewing the three pictures had difficulty freely recalling one or two of the pictures (one and two subjects, respectively), while two of the subjects recognized only two of the three pictures out of a group of 12 pictures. A tentative conclusion may be that some degree of retrograde amnesia occurs within a one-minute time frame prior to the administration of Midazolam, as well as Thiopental. Two subjects in the one-minute Thiopental group recalled only 2 out of 3 pictures, while fully recognizing all 3 pictures when shown a group of 12 pictures.

89-30 Continued

Preliminary conclusion: It appears that subjects in the subgroup receiving Midazolam one minute after viewing the three pictures had difficulty freely recalling one or two of the pictures (one and two subjects, respectively), while two of the subjects recognized only two of the three pictures out of a group of 12 pictures. A tentative conclusion may be that some degree of retrograde amnesia occurs within a one-minute time frame prior to the administration of Midazolam, as well as Thiopental. Two subjects in the one-minute Thiopental group recalled only 2 out of 3 pictures, while fully recognizing all 3 pictures when shown a group of 12 pictures.

Detail Summary Sheet

Date: 10 Oct 90 Prot No.: 90-14		Status: Ongoing
Title: A Comparative Study of Nitrous Oxide and the Incidence of Postoperative Emetic Symptoms.		
Start Date:		Est Comp Date:
Principal Investigator(s) Ronald Eslick, CPT, AN		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Anesthesia Course		Associate Investigators: Tony Singh, CPT, AN Jeffrey White, CPT, AN Dale Willenberg, CPT, AN John Woodward, CPT, AN
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if use of nitrous oxide for the maintenance of general anesthesia is associated with an increased incidence of postoperative nausea and vomiting.

Technical Approach: The study was conducted as a quasi-experimental study. Two study groups were selected. Group 1 consisted of subjects receiving N2O/O2/Forane. Group 2 consisted of subjects receiving Air/O2/Forane. The two groups were utilized to compare the effects of the previously mentioned anesthetics and their relationship to postoperative nausea and vomiting.

Manpower: five nurse anesthesia student investigators and recovery room personnel ranging in number from 3-6 ANCs and 91Cs.

Funding: none.

Number of subjects enrolled to date: 70

With the exception of postoperative nausea and vomiting, no significant adverse reactions were noted during the study period.

Progress: To date, a total of 70 subjects have participated in the study. Of these individuals 37 (52.8%) received a nitrous oxide/oxygen/forane mixture, while 33 individuals (47.2%) received a combination of air/oxygen/forane. Preliminary findings indicate a < 1% incidence of postop nausea and vomiting in both groups. However, a more concise breakdown will follow with the conclusion of the study.

Detail Summary Sheet

Date: 23 Oct 90 Prot No.: 90-25		Status: Ongoing
Title: A Prospective Randomized Study of the Prophylaxis of Thromboembolism Dihydroergotamine/Heparin Versus Sodium Warfarin in Total Joint Patients		
Start Date: Jun 90		Est Comp Date:
Principal Investigator(s) David A. Volgas, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic Surgery		Associate Investigators: H. Stan Reid LTC, MC Melissa McMillan, MAJ, MC Robert Scharstein, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare two regimens commonly used for thromboembolism prophylaxis in the total joint patient.

Technical Approach: Number of subjects enrolled to date: 10

Progress: Ten patients to date have completed the study protocol. There have been no positive results from either the pre-op or post-op ultrasound studies. There has been one incidence of post-op bleeding in excess of the normal (coumadin) and in one instance coumadin was reversed secondary to prolonged PT/PTT. Both complications were treated without ill effects to the patients and indeed are recognized complications of anti-coagulant therapy. No transfusions other than what is normal for total joint patients have been required. Currently there are six more patients scheduled for total joint surgery before the end of the year who will be enrolled in the study if they agree.

Detail Summary Sheet

Date: 23 Oct 90 Prot No.: 90-26		Status: Ongoing
Title: The Relationship of the Sense of Coherence and Hardiness to the Nutritional Status of Anorectic Head and Neck Cancer Patients Currently Undergoing Radiation Therapy.		
Start Date: Jun 90		Est Comp Date:
Principal Investigator(s) Loretta Forlaw, LTC, AN		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Otolaryngology		Associate Investigators: Gary R. Burch, MD, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To investigate the relationship of the sense of coherence and hardiness to the nutritional status of anorectic head and neck cancer patients.

Technical Approach:

Progress: One patient enrolled from Eisenhower, no data has been done yet.

Detail Summary Sheet

Date: 10 Sep 90 Prot No.: 90-32 Status: Ongoing

Title: Training General Surgery Residents Utilizing Goat Models

Start Date:		Est Comp Date:
Principal Investigator(s) Stephen Gooden, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Clinical Investigation		Associate Investigators: Michael P. Byrne, LTC, MC Robert Martindale, MAJ, MC Manuel Ramirez, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To allow the practicing and refinement of surgical approaches and techniques on animal models prior to performing the same procedure in the human.

Progress: Study not yet started.

Detail Summary Sheet

Date: 18 Sep 90 Prot No.: 90-37		Status: Ongoing
Title: The Influence of Human Growth Hormone on Post-Operative Recovery Following Major Upper Abdominal Surgery		
Start Date:		Est Comp Date:
Principal Investigator(s) Robert G. Martindale, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery		Associate Investigators: Michael P. Byrne, MD, LTC, MC Stephen Gooden, MD, LTC, MC Ross S. Davies, MD, COL, MC Arnold A. Asp, MD, MAJ, MC Michael J. Kottas, MAJ, MS
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To use hormonal manipulation to lessen the lean body tissue loss associated with a major catabolic insult.

Technical Approach: Patients will be randomized to receive either standard post operative care and nutritional support (control) or standard care plus addition of GH (recombinant human growth hormone) starting the day prior to surgery.

Progress: Local approval in Sep, no reportable data.

Detail Summary Sheet

Date: 11 Oct 90	Prot No.: 78-14	Status: Ongoing

Title: Intraocular Lens Study.

Start Date: Nov 80		Est Comp Date:
Principal Investigator(s) Robert A. Mazzoli, MD, MAJ, MC		Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Surgery/Ophthalmology		Associate Investigators: Elizabeth A. Hansen, MD, MAJ, MC Steven L. Henslee, MD
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical insertion of intraocular lens. Presently, intraocular lenses selected for implantation include IOLAD Model G108B, 3M Vision Care Style 83, Precision-Cosmet Model 8201, and Cilco Styles SK21VO, SAC5VO.

Number of subjects enrolled to date: 679
Number of subjects enrolled for reporting period: 78

Progress: All lenses are FDA approved; case registration performed as part of adjunct safety study.

Detail Summary Sheet

Date: 11 Oct 90 Prot No.: 86-26		Status: Ongoing
Title: A Randomized, Controlled Trial of Initially Treated Corneal Abrasions: Physician Mandated Every 24 Hours Follow-Up Versus Patient Initiated (PRN) Follow-Up.		
Start Date: Jul 86		Est Comp Date:
Principal Investigator(s) Ted D. Epperly, MD, MAJ, MC		Facility: USAMEDDAC, Ft Benning, GA
Dept/Svc: Family Practice		Associate Investigators: Mark A. Connelly, MD, MAJ, MC Steven E. Reissman, DO, MAJ, MC Frank Celestino, MD, Bowman Gray School of Med, Winston Salem, SC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if patients need to be checked on a daily basis for healing of their corneal abrasion versus a PRN approach to follow-up if symptoms/signs develop.

Technical Approach: This study will be a randomized, prospective controlled trial involving patients with uncomplicated corneal abrasions. A full eye exam will be done on all patients and all patients will then be treated in a standardized fashion. Patients will then be randomized into two groups for follow-up: Group 1 will receive daily follow-up and reexamination until healing is documented (negative flourescein) and symptoms are gone. Group 2 will be instructed to leave patch on for 36 hours and then remove. Upon patch removal, follow-up will be PRN and patient-initiated based on the patient's perception of persistent bothersome symptoms. Data will be analyzed using the chi-squared methodology for dichotomous variables. The measured outcome variables will be number of re-visits, complications, and days of symptoms in each group.

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0

Progress: Due to other commitments, study has not been started. Protocol to be updated and resubmitted.

Detail Summary Sheet

Date: 11 Oct 90 Prot No.: 89-35 Status: Completed

Title: The Effects of Maternal IV Fluid During Routine Labor

Start Date:	Est Comp Date:
Principal Investigator(s) Mark A. Connelly, MD, MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice	Associate Investigators: Ted D. Epperly, MD, MAJ, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if dextrose or non-dextrose containing IV fluids affect fetal blood sugars.

Technical Approach:

Number of subjects enrolled: 110

Progress: Data collection stopped August 1989. Paper in final review.

Detail Summary Sheet

Date:11 Oct 90	Prot No.: 89-36	Status: Terminate

Title: Assertiveness, Emotional Expressiveness and Gender Role in Relation to Preference for Counseling Approach

Start Date:		Est Comp Date:
Principal Investigator(s) Michael J. Blier, PhD		Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice		Associate Investigators: Linda Blier-Wilson
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Examine relationships between interpersonal skills and reactions to different counseling approaches. Also look at characteristics of spouse abusers.

Technical Approach: Subjects participating to date: 135 out of 200 needed. No adverse or significant reactions noted to date.

Number of subjects enrolled: 135

Progress: Report not submitted by investigators, terminate.

Detail Summary Sheet

Date: 31 Oct 90 Prot No.: 90-20		Status: Completed
Title: Duration of Heat Intolerance Following Heat Stroke.		
Start Date:		Est Comp Date:
Principal Investigator(s) Jennifer Calagan, MAJ, MC		Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice		Associate Investigators: Ted Epperly, MAJ, MC Tim Landes, MAJ, MC Kevin Lokkesmoe, CPT, MC Nadja West, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective:

Study suspended by HSC.

Detail Summary Sheet

Date: 10 Oct 90	Prot No.: 78-14	Status: Ongoing

Title: Intraocular Lens Study.

Start Date: Oct 81		Est Comp Date:
Principal Investigator(s) Emil A. Stein, MD, CPT, MC		Facility: USA MEDDAC, Ft Campbell, KY
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To provide to cataract patients the latest development in ophthalmic surgery concerning the correction of surgical aphakia.

Technical Approach: Extracapsular cataract extraction followed by the implantation of an intraocular lens implant.

Subjects enrolled to date: 190
Subjects enrolled for the reporting period: 59

Progress: Cataracts removed and lenses implanted without any unusual complications. Visual improvement postop in all patients to some degree, most marked improvement.

Detail Summary Sheet

Date: 10 Oct 90 Prot No.: 78-14A		Status: Ongoing
Title: Pediatric Intraocular Lens Study		
Start Date: Jan 90		Est Comp Date:
Principal Investigator(s) Emil A. Stein, MD, MAJ, MC		Facility: USA MEDDAC, Ft Campbell, KY
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To provide pediatric patients with the latest development in ophthalmic surgery for the treatment of surgical aphakia.

Technical Approach: Extracapsular cataract extraction followed by implantation of an intraocular lens implant.

Number of subjects enrolled to date: 1

Progress: Va improved from $20/80^{+1}$ to 20/25 uncorrected at 79 days postop. No postop problems.

Detail Summary Sheet

Date: 10 Oct 90 Prot No.: 88-35		Status: Terminate
Title: A Comparison of Hydrocortisone Phonophoresis Using Pulsed versus Continuous Ulstrasound for the Treatment of Lateral Epicondylitis		
Start Date: Sep 88		Est Comp Date:
Principal Investigator(s) Jan W. Durst, 2LT, SP		Facility: USA MEDDAC, Ft Campbell, KY
Dept/Svc: Surgery/ Physical Therapy Clinic		Associate Investigators: Francis J. Pottenger, CPT, SP Barry L. Karalfa, CPT, SP
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the clinical use of HCP in the treatment of lateral epicondylitis; to evaluate differences in the clinical effectiveness of HCP delivered with continuous and pulsed ultrasound; and to provide further validation or invalidate the use of the McGill Pain Questionnaire for lateral epicondylitis through correlation with quantitative strength data.

Technical Approach: Patients meeting the screening criteria for the diagnosis of lateral epicondylitis will be asked to participate in the study. Subjects will be randomly assigned into four gruops: one to receive HCP using pulsed ultrasound, one to receive HCP using continuous ultrasound, one receiving pulsed ultrasound with a non-medicated gel, and one receiving continuous ultrasound with a non-medicated gel. All other aspects of rehabilitation program will be standardized. Prior to treatment and following the treatment regimen, the subjects will complete the McGill Pain Questionnaire and have their strength evaluated on the Cybex system. Statistical analysis on the pre- and post-treatment wrist extensor strength and perceived pain quotients will be performed.

Progress: No response from investigator, terminate.

Detail Summary Sheet

Date: 12 Sep 90 Prot No.: 88-20		Status: Terminated
Title: A Phase III, Randomized, Double Blind, Placebo-Controlled Study of 5-Fluorouracil, With or Without Large Doses of Sellcovorin (Leucovorin Tablets), in Measurable Metastatic Colon and Rectal Carcinoma		
Start Date:		Est Comp Date:
Principal Investigator(s) Steven Madden, M.D.		Facility: USA MEDDAC, Ft Jackson, SC
Dept/Svc: Medicine/Oncology		Associate Investigators: George P. Sartiano, M.D.
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether measurable metastatic colon and rectal carcinoma patients can benefit from oral Leucovorin tablets combined with 5-Fluorouracil chemotherapy.

Technical Approach:

Number of subjects enrolled to date: 0
Number of subjects enrolled during reporting period: 0

Progress: Terminate per investigator's instructions.

Detail Summary Sheet

Date: 12 Sep 90 Prot No.: 89-26		Status: Terminated
Title: The Utility of Thermographic Evaluation in the Diagnosis of Lower Extremity Injuries During Army Initial Entry Training		
Start Date: Apr 89		Est Comp Date:
Principal Investigator(s) Margarete DiBenedetto, COL, MC		Facility: USAMEDDAC, Ft Jackson, SC
Dept/Svc: Physical Medicine		Associate Investigators: Murray Hamlet, DVM Bruce H. Jones, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the utility of thermographic evaluation to detect the presence or absence of commonly occurring lower extremity injuries associated with Army initial entry training.

Technical Approach:

Number of subjects enrolled to date: 0
Number of subjects for the reporting period: 0

Progress: Study was conducted at Ft Bliss as a like protocol, no work was done at Ft Jackson. Terminate.

Detail Summary Sheet

Date: 11 Oct 90	Prot No.: 89-32	Status: Terminated

Title: Correlation of Clinical Hip Examination Findings with Scintigraphic and Radiographic Results in Army Trainees with Hip Pain.

Start Date:		Est Comp Date:
Principal Investigator(s) Gary J. Hague, CPT, SP		Facility: USA MEDDAC, Ft Jackson, SC
Dept/Svc: Surgery/Physical Therapy		Associate Investigators: Theresa M. Nemmers, MAJ, SP Scott VanDenhengel, CPT, SP Timothy Gangel, 1LT, SP Paul Behrens, 1LT, SP
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: a) What correlation exists between clinical findings/ assessment and scintigraphic/radiographic findings for stress reactions about the hip? b) At what time in the training cycle do trainees first relate onset of symptoms in cases of stress reaction/fractures about the hip? c) What patient characteristics correlate with incidence of stress reactions about the hip?

Technical Approach: Subjects presenting to the Physical Therapy Clinic, McWethy TMC reporting hip, groin, or thigh pain and having completed greater than two weeks of training will be asked to participate in the study. Subjects will be examined by a staff physical therapist utilizing the standard hip examination form. Patients will then be asked to complete a study questionnaire. Patients with minimal findings on hip examination will be treated conservatively. Conservative treatment will be for no greater than ten days. Patients with persistent hip pain despite conservative treatment and patients with significant findings on hip examination will receive a radiographic procedure. Those subjects with radiographs inconclusive for stress reactions/fractures will be further evaluated with a scintigraphic procedure. Following completion of the scintigraphs or radiographs, if conclusive for stress reaction/fracture, the subject will be included in the study. Results of scintigraphs will be interpreted by the Chief, Nuclear Medicine. Final definitive correlation on all abnormal scintigraphs or radiographs will be made by a staff orthopedist.

Number of subjects enrolled to date: 70
Number of subjects enrolled for reporting period:
No adverse reactions were observed.

Progress: Report not submitted by investigators, terminate.

Detail Summary Sheet

Date: 10 Oct 90 Prot No.: 90-15		Status: Ongoing
Title: Predicting Preventive Health Behaviors in Sexually Active Women: A Pilot Study.		
Start Date:		Est Comp Date:
Principal Investigator(s) Ellen Adams, MAJ, AN		Facility: Moncrief Army Community Hospital
Dept/Svc: Gynecology Clinic		Associate Investigators: Elizabeth Abel, RN
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To develop a correlational model that predicts women's sexual behaviors for chlamydia and to determine the reliability and validity of the instruments.

Progress: The project has been delayed. Data collection is scheduled to commence in Sep 90. A more in-depth report will be available in FY 91.

Detail Summary Sheet

Date: 2 Nov 90 Prot No.: 90-21		Status: Terminated
Title: Dietary Calcium as a Risk Factor for Stress Reactions in Female US Army Trainees		
Start Date: May 90		Est Comp Date:
Principal Investigator(s) Robin Tefft, MAJ, SP		Facility: USA MEDDAC, Ft Jackson, SC
Dept/Svc: Nutrition Care		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To analyze whether a difference in stress fracture risk exists between two groups of trainees.

Technical Approach:

Progress: The study was terminated in September 1990 with no data collected. The questionnaire was too complicated for self completion by subjects. It was not feasible to collect the data through interview.

Detail Summary Sheet

Date: 10 Oct 90	Prot No.: 89-7	Status: Terminate

Stress Fractures in Military Trainees with Irregular Menstrual Patterns.

Start Date:		Est Comp Date:
Principal Investigator(s) Leanne Lyon, CPT, SP		Facility: USA MEDDAC, Ft McClellan, AL
Dept/Svc: Physical Therapy		Associate Investigators: Gloria T. Sanders, LTC, SP Stephen Layman, 1LT, SP Joicey M. Putnam, COL, SP
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To answer the following: 1) What is the incidence of stress fractures in female military trainees with irregular menstrual frequency (historically and during training)? 2) What is the risk of acquiring a stress fracture in a female military trainee with decreased historical or training menstrual frequency? 3) In females with decreased menstrual frequency and a stress fracture, will follicle-stimulating hormone (FSH), luteinizing hormone (LH), estradiol, and phosphorus (Pi) be decreased and simultaneously, will calcium and parathyroid hormone (PTH) be increased when compared to their controls? 4) Will females with decreased menstrual frequency have more stress fracture and decreased FSH, LH, Pi, and estradiol; increased PTH and calcium when compared to females with regular menstrual cycles and stress fractures? 5) Will the stress fracture group as a whole have decreased FSH, LH, Pi, and estradiol; and increased PTH and calcium when compared to the control group regardless of menstrual cycle irregularity?

Technical Approach: This is a case control study. Manpower requirements include the use of the existing lab at TMC #3 for drawing samples, 1-2 physical therapists for data collection and the use of BAMC and DDEAMC laboratories for blood analysis. No significant adverse reactions have occurred.

Number of subjects enrolled to date: 24
Number of subjects enrolled for reporting period:

Progress: The principal investigator for this project left military service November 1989. No information was passed on to the associate investigator, and no record of data exists.

Detail Summary Sheet

Date: 20 Sep 90 Prot No.: 78-14		Status: Terminate
Title: Intraocular Lens Study.		
Start Date: Feb 88		Est Comp Date:
Principal Investigator(s) Eugenio F. Bird, MD, MAJ, MC		Facility: USA MEDDAC, Ft Polk, LA
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical implant of intraocular lens.

Number of subjects enrolled to date: 39
Number of subjects enrolled for reporting period: 0

Progress: Investigational lenses were not implanted during reporting period, terminate.

Detail Summary Sheet

Date: 19 Sep 90 Prot No.: 78-14 Status: Terminate
Title: Intraocular Lens Study.

Start Date: Oct 80		Est Comp Date:
Principal Investigator(s) William F. Varr, MD, MAJ, MC		Facility: USA MEDDAC, Ft Rucker, AL
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words: Intraocular Lens Aphakia Implant Surgery Ophthalmology		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: The objective of the ongoing FDA study is to determine the safety of the intraocular lens implant in the human eye.

Technical Approach: Lenses in use are Cilco SK 21-UO, and MTU which are not experimental.

Subjects enrolled to date: 452
Subjects enrolled for reporting period: 0

Progress: Investigational lenses were not used during the reporting period, terminate at investigator's request.

Detail Summary Sheet

Date: 18 Sep 90 Prot No.: 90-38		Status: Ongoing
Title: Comparison of Cefpodoxime Proxetil and Ciprofloxacin in the Treatment of Acute Pneumonia in Geriatric Patients		
Start Date:		Est Comp Date:
Principal Investigator(s) John A. Powell, MD, MAJ, MC		Facility: USA MEDDAC, Ft Rucker, AL
Dept/Svc: Medicine		Associate Investigators: Jeff Stone, MD, LMAJ, MC Paul Hunn, MD, CPT, MC Roland J. Weisser, Jr., LMD, COL, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the efficacy and safety of orally administered cefpodoxime proxetil and ciprofloxacin in the treatment of acute pneumonia caused by pathogens susceptible to these two antimicrobials, in geriatric patients.

Technical Approach: This is a randomized, comparative, observer-blinded, parallel-treatment, multicenter study evaluating efficacy and safety of cefpodoxime proxetil in acute pneumonia. patients will be selected based on signs and symptoms of pneumonia caused by organisms expected to be susceptible to cefpodoxime proxetil and ciprofloxacin.

Progress: Pending HSC approval.

Detail Summary Sheet

Date: 10 Sep 90	Prot No.: 78-14	Status: Terminated

Title: Intraocular Lens Study.

Start Date: Nov 84		Est Comp Date:
Principal Investigator(s) Mark H. Cook, MD, MAJ, MC		Facility: USA MEDDAC, Ft Stewart, GA
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $9000	Periodic Review Results

Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical insertion of intraocular lens.

Number of subjects enrolled to date: 109
Number of subjects enrolled for reporting period: 0

Progress: Investigator left the service, terminate.

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